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In the Supreme Court of the United States

OCTOBER TERM, 1974

UNITED STATES OF AMERICA, PETITIONER

v.

JOHN R. PARK

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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The Solicitor General, on behalf of the United States, petitions for a writ of certiorari to review the judgment of the Court of Appeals for the Fourth Circuit in the above-captioned case.

OPINION BELOW

The opinion of the court of appeals (App. A, *infra*, pp. 1A–12A) is not yet officially reported.

JURISDICTION

The judgment of the court of appeals (App. B, *infra*, p. 13A) was entered on July 2, 1974. On July 26, 1974, Mr. Chief Justice Burger extended the time within which to file a petition for a writ of certiorari to and including August 31, 1974. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether, in a prosecution of a corporate officer for doing or causing acts resulting in the adulteration of food, an instruction that the jury may convict if it finds that the defendant had a responsible relation to the situation, but which does not also require a finding of particular acts of omission or commission or gross negligence by the officer, accords with the standards of *United States* v. *Dotterweich*, 320 U.S. 277.

2. Whether evidence that the president of a supermarket chain was on notice of insanitary conditions in his firm's Philadelphia warehouse in March 1970, was admissible to rebut his defense of justifiable reliance on subordinates, or to show his failure adequately to supervise them, with respect to insanitary conditions in the chain's Baltimore warehouse in 1971 and 1972.

STATUTE INVOLVED

Section 301(k) of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1042, as amended, 21 U.S.C. 331(k), provides:

> The following acts and the causing thereof are prohibited:
>
> * * * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

STATEMENT

In a five-count information filed in the United States District Court for the District of Maryland, the United States charged Acme Market, Inc., a large food store chain, and respondent, its president, with violating Section 301(k) of the Food, Drug, and Cosmetic Act, *supra*, p. 2. The information alleged that the defendants had received food that had been shipped in interstate commerce and held for sale in Acme's Baltimore warehouse following the interstate shipment, and that, because Acme's Baltimore warehouse was infested by rodents, the defendants had caused the food to be adulterated by being exposed to contamination by rodents.[1]

Each count of the information charged that the food was adulterated because it consisted in part of a filthy substance and was rodent-gnawed (see 21 U.S.C. 342 (a)(3)) and because the food was held under insanitary warehouse conditions whereby it may have become contaminated (see 21 U.S.C. 342(a)(4)).

Acme entered a plea of guilty to each count of the information. On May 10, 1973, after a jury trial, respondent was found guilty on all five counts of the information, and was subsequently sentenced to pay a total fine of $250.

1. At trial, the government introduced evidence establishing that the adulterated food had been

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[1] Acme is a nationwide food store chain that employs approximately 36,000 persons and does business through 874 retail outlets. The company has twelve main warehouses and four special warehouses located in various parts of the country. The company headquarters, including respondent's office, is located in Philadelphia, Pennsylvania (App. A, *infra*, p. 5A, n. 5).

shipped in interstate commerce and was being held for sale in the Baltimore warehouse. An inspector from the Food and Drug Administration testified that he inspected this warehouse in November and December 1971 and found extensive evidence of rodent infestation (J.A. 20–22).[2] Following this inspection, FDA sent respondent a letter advising him of the conditions at the Baltimore warehouse (J.A. 30, Exh. 23). Robert W. McCahan, Baltimore Divisional Vice-President, responded to the letter on behalf of respondent (J.A. 32, Exh. 24). A second inspection by FDA in March 1972 revealed further evidence of rodent infestation (J.A. 22–23). The first four counts of the information (App. A, *infra,* p. 2A) described violations discovered during the inspection in November and December 1971, while the fifth count described violations discovered during the inspection in March 1972 (*ibid.*).

McCahan testified that he replied to the FDA letter on behalf of respondent (J.A. 35). Acme's general counsel identified respondent as the president and chief executive officer of Acme and read the company bylaws describing respondent's duties. The bylaws provide that the chief executive officer "shall, subject to the board of directors, have general and active supervision of the affairs, business, offices and employees of the company" (J.A. 40).

Respondent was the only defense witness. He testified that, while all company employees were under his direction, he employed a system of delegated respon-

[2] "J.A." refers to the Joint Appendix filed in the court of appeals.

sibilities under which he had delegated the responsibility for dealing with sanitation problems to various other persons within the corporation (J.A. 43–46). He admitted that he had seen the letter sent to him by FDA following the first inspection, advising him of the conditions at the Baltimore warehouse, but stated that he had delegated the responsibility of investigating the situation to McCahan (J.A. 46–48).

On cross-examination, respondent admitted that he had received and read a letter from FDA dated April 24, 1970 (J.A. 53–55). This letter (Exh. 27) stated that evidence of rodent infestation had been found in Acme's Philadelphia Warehouse.[3] Respondent acknowledged that, with the exception of the divisional vice-president, the same corporate officials have responsibility for sanitation in both Baltimore and Philadelphia (J.A. 55–56). He also conceded that sanitation problems occurred in Philadelphia and then again in Baltimore, that these incidents indicated that his system for handling sanitation matters was not working perfectly, and that he had the ultimate responsibility to make whatever changes were necessary to make the system work (J.A. 56–57).

The district court instructed the jury on the issue of respondent's responsibility as follows (J.A. 64):

> The statute makes individuals, as well as corporations, liable for violations. An individual is liable if it is clear, beyond a reasonable doubt, that the elements of the adulteration of the food as to travel in interstate commerce are present.

[3] Respondent objected to all questions concerning the Philadelphia incident.

> As I have instructed you in this case, they are, and that the individual had a responsible relation to the situation, even though he may not have participated personally.
>
> The individual is or could be liable under the statute, even if he did not consciously do wrong. However, the fact that the Defendant is president[4] and is a chief executive officer of the Acme Markets does not require a finding of guilt. Though, he need not have personally participated in the situation, he must have had a responsible relationship to the issue. The issue is, in this case, whether the Defendant, John R. Park, by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose.

Respondent objected to this instruction on the ground that it was not consistent with this Court's decision in *United States* v. *Dotterweich*, 320 U.S. 277 (J.A. 64–65). The jury returned a verdict of guilty on all five counts of the information (J.A. 2).

2. A divided panel of the court of appeals reversed the judgment of conviction and remanded the case for a new trial. The majority held that the jury instruction "might well have left the jury with the erroneous impression that Park could be found guilty in the absence of 'wrongful action' on his part" (App. A, *infra*, p. 5A). The court stated that the requisite "wrongful action" could consist of respondent's "gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' the contamination of the food" (*id.* at 6A), but that respondent could not be found guilty simply because of "his relation to the corporation" as its president (*id.* at 5A).

[4] Although the transcript says "present," the court obviously meant, and presumably said, "president."

The court also held that testimony concerning the Philadelphia incident should have been excluded as being unduly prejudicial (*id.* at 8A), although the court nevertheless suggested that the testimony might be admissible at retrial depending upon "the prosecution's new approach to the presentation of its case" (*id.* at 9A) and the district court's application of the standards for admission of evidence of prior offenses set forth in the court's recent decision in *United States* v. *Woods*, 484 F. 2d 127, 134 (C.A. 4) (App. A, *infra* pp. 7A–8A).

Judge Craven dissented on the ground that the majority opinion was inconsistent with *United States* v. *Dotterweich, supra*. He concluded that the government had presented sufficient evidence to send the case to the jury and that the jury was properly instructed. He also noted that the government had not argued to the jury that it could find the defendant guilty simply because he is the head of the company (App. A, *infra*, pp. 9A–12A).

REASONS FOR GRANTING THE WRIT

In *United States* v. *Dotterweich*, 320 U.S. 277, this court held that individual corporate officers and employees, as well as corporations, may be convicted for doing or causing the acts prohibited in Section 301 of

the Federal Food, Drug and Cosmetic Act of 1938 (52 Stat. 1042, as amended, 21 U.S.C. 331). In that decision, the Court also construed the standard of responsibility laid down by Congress for the officers and agents through whom corporations handling food and drugs must act: a person standing "in responsible relation" to the prohibited acts may be criminally liable for their occurrence even though he is not aware of the wrongdoing. 320 U.S. at 281.

Thus, officials of business entities whose activities affect the public health have been subjected to one of the highest standards of public accountability. This standard, unchanged by Congress, has protected the public for more than 30 years since *Dotterweich*. The decision of the court of appeals in this case, however, has lowered the level of accountability defined in *Dotterweich* by adding a new element—a requirement of a finding that the responsible corporate official also be guilty of gross negligence or other particular acts of omission or commission causing the violation (App. A, *infra*, p. 6A). This ruling conflicts with *Dotterweich* and decisions of other courts applying *Dotterweich*. Moreover, it defeats the purpose of Congress in enacting Section 301 by inviting corporate executives to insulate themselves from active supervision of matters vitally affecting the public health, and by diffusing responsibility for such matters.

1. Despite this Court's warning in *Dotterweich* that, in construing Section 301, "[l]iteralism and evisceration are equally to be avoided" (320 U.S. at 284), the court of appeals gave an unduly rigid reading to Section 301(k), the provision involved here. That section

prohibits the "doing" or the "causing" of any "act with respect to, a food, * * * if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated * * *." The court of appeals concluded that liability under this statute requires proof of some "wrongful" act.

Dotterweich is to the contrary. That case involved prosecution under Section 301(a) of a drug jobbing corporation, and its president and general manager, Dotterweich, for shipping misbranded drugs in interstate commerce. A jury failed to agree as to the corporation, but nevertheless convicted Dotterweich as the responsible corporate officer even though he had no personal knowledge of the misconduct involved, and there was no evidence of any "personal guilt" on his part. 320 U.S. at 286 (Murphy, J. dissenting). The court of appeals set aside the conviction on the ground that only the corporation could be convicted for the offense charged. In reinstating the conviction, this Court defined standards of corporate and individual responsibility imposed by Section 301 which are now regarded as fundamental in the food and drug industries.

The Court held, first, that the statute "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. *United States* v. *Balint*, 258 U.S. 250." 320 U.S. at 281.

Second, it rejected a reading of the statute based upon fears that it "might" operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment" (*id.* at 284). As the Court stated (*ibid.*):

> To speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid or abet its commission are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance. The offense is committed, unless the enterprise which they are serving enjoys the immunity of a guaranty, by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs. * * *

Third, the Court recognized the practical consequences of the high standard it was adopting, and found support for it in the balance struck by Congress between the relative situations of the corporate official in a position to learn of problems in the business he is running, and that of consumers who might innocently suffer grave injuries to their health (*id.* at 284–285):

> Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

The decision in *Dotterweich* thus rested on Congress' clear purpose to impose upon corporate officers with supervisory responsibilities an affirmative duty to assure that food and drugs are not adulterated or misbranded. The Court eschewed any attempt to define or clarify "the variety of conduct whereby persons may responsibly contribute in furthering a [violation of the Act]." *Id.* at 285. Rather, it held that "[i]n such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted." *Ibid.* The question of individual responsibility, therefore, is properly a matter for the jury in the light of its assessment of evidence showing the individual defendant's duties within his firm.

These criteria have been followed in numerous cases. For example, in *H. B. Gregory Co.* v. *United States,* No. 73–1744 (C.A. 7), decided March 14, 1974, pending on petition for a writ of certiorari, No. 74–142, the Court of Appeals for the Seventh Circuit expressly rejected a contention that the strict personal liability recognized in *Dotterweich* was an improper legal standard because it "fails to require a causal relation between the individual and the violation of the Act." Slip op. p. 8. See also *United States* v. *Shapiro,* 491 F. 2d 335, 337 (C.A. 6); *United States* v. *Cassaro, Inc.,* 443 F. 2d 153, 157 (C.A. 1); *Lelles* v. *United States,* 241 F. 2d 21, 22–25 (C.A. 9), certiorari

denied, 353 U.S. 974; *United States* v. *Kaadt,* 171 F. 2d 600, 604 (C.A. 7); *United States* v. *Parfait Powder Puff Co.,* 163 F. 2d 1008 (C.A. 7), certiorari denied, 332 U.S. 851; *United States* v. *Diamond State Poultry Co.,* 125 F. Supp. 617, 619, 620 (D. Del.).

Moreover, the principles of *Dotterweich* that are controlling here have been reiterated and reaffirmed by this Court in *United States* v. *Wiesenfeld Warehouse Co.,* 376 U.S. 86, 91, and *United States* v. *Freed,* 401 U.S. 601, 609.

The court below purported to distinguish *Dotterweich* on two grounds. First, it emphasized the size of the supermarket chain of which respondent was president and chief executive officer (see p. 3, *supra,* n. 1). But nothing in *Dotterweich* indicates that a corporation's size is an exculpatory factor; the test of constructive participation is official responsibility, whether the corporation be large or small. Assessment of that responsibility, in the light of such facts as the corporation's size and other defensive matters raised at trial, is a matter for the jury under proper intructions. See *United States* v. *Wiesenfeld Warehouse Co., supra.*

Second, the court of appeals relied upon a sentence in *Dotterweich* suggesting that all who aid and abet a corporation in commission of an offense are equally guilty. 320 U.S. at 284. Read in context, however, that language was intended simply to emphasize the concept of individual responsibility, not to restrict the independent offense, so carefully defined in Section 301, to prosecutions for aiding, abetting or conspiring with the corporation.[5] This is shown by the fact that it was not fatal to the validity of the officer's conviction in *Dotterweich* that the jury had disagreed as to the guilt of the corporation.

The jury instructions upheld by this Court in *Dotterweich* (320 U.S. at 285) show that proof of a wrongful act by a corporate official is not necessary to establish his liability under Section 301.[6] These instructions did not require the jury to find "wrongful action," but simply to determine responsibility. Similarly, the charge in the instant case instructed the jury to determine whether respondent "had a position of authority and responsibility in the situation out of which these charges arose" (Statement, *supra,* p. 6).

As Judge Craven recognized in his dissent, the government has never argued that respondent is guilty of

[5] 18 U.S.C. 2(a) provides:

"Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission, is punishable as a principal."

[6] The district court in the *Dotterweich* case instructed the jury as follows:

"We also have as a defendant here, Joseph Dotterweich. As far as the question of his guilt regarding the charges in the information is concerned, the question is, if you find the product to be misbranded and adulterated, 'Was he responsible for the shipment of them in interstate commerce?' In other words, are you satisfied from the evidence that the shipment of the cascara compound and the shipment of the digitalis were made under his supervision by him as 'General Manager.' It is not necessary for the Government to prove that he personally and physically made the shipment himself. It is sufficient if the evidence establishes to your satisfaction that it was made under authority conferred by him as general manager upon his subordinates, including the receiving and shipping clerk." (Record on Appeal in *United States* v. *Joseph H. Dotterweich* at 164.) See also *United States* v. *Kaadt, supra,* 171 F. 2d at 604.

violating Section 301 solely because he is president of the corporation. As the trial judge noted in his instructions (Statement, *supra,* p. 6) corporate titles do not necessarily prove responsibility for the situations resulting in violation of the Act. Rather, the government must offer proof of actual supervisory responsibility relating to the prohibited acts. It did so in this case, and it was, accordingly, for the jury to determine, in the light of that proof and respondent's exculpatory evidence, whether he was in fact responsible.[7] The decision of the court below to the contrary would substantially curtail the effectiveness of both (1) the government's enforcement program under the Food, Drug and Cosmetic Act and (2) that Act's inducement of responsible corporate self-policing on which the protection of the public in this field so largely depends.

2. Respondent testified in his own defense that he had employed a system in which he relied upon his subordinates to handle sanitation problems, for which he acknowledged ultimate responsibility. On cross-examination, the government showed that twenty months before discovery of the unsanitary conditions alleged to exist at Acme's Baltimore warehouse, FDA

[7] Although the court of appeals has remanded the instant case for retrial under its new standard, there is no assurance that adverse decisions of lower courts applying that standard will be appealable by the government. If the government fails to present proof of "wrongful conduct," the trial court may grant a motion for acquittal. Under the double jeopardy clause, such a judgment might not be appealable by the government. See *United States* v. *Ball*, 163 U.S. 662, 671; *Fong Foo* v. *United States*, 369 U.S. 141; *United States* v. *Sisson*, 399 U.S. 267. But see *United States* v. *Jenkins*, No. 73-1513, certiorari granted, May 28, 1974.

had given respondent notice of unsanitary conditions in the firm's warehouse at Philadelphia. This testimony tended to show that respondent was on notice that he could not rely upon his system of delegation to subordinates to prevent unsanitary conditions in the firm's warehouses, that he was aware of the deficiencies of this system before the Baltimore violations were discovered, and that he had the responsibility and power to take steps to insure that it worked in compliance with the Act. Cf. *United States* v. *Ross,* 321 F. 2d 61, 67 (C.A. 2), certiorari denied, 375 U.S. 894; *United States* v. *Kaufman,* 453 F. 2d 306, 310–311 (C.A. 2).

The panel majority viewed this evidence as if it were evidence of an unprosecuted prior crime, the admissibility of which depended on a balancing of prejudice to the defendant against the needs of justice. See *United States* v. *Woods, supra,* 484 F. 2d at 134–135. The court found that the evidence was prejudicial and that no need for it had been shown under the theory on which this case was tried. The evidence demonstrated, however, both respondent's awareness of prior sanitation deficiencies in Acme's warehouse sanitation system, and his admitted responsibility for correcting them, thus tending to rebut his defense that he had justifiably relied upon subordinates to handle sanitation matters. This evidence was therefore directly relevant to the jury's determina-

tion of whether respondent shared the responsibility for the conditions in issue.[8]

Under the standard adopted by the court of appeals here, corporate officials would be encouraged to avoid the active supervision necessary to protect the public from adulterated food and drugs. As construed in *Dotterweich*, however, the Act was intended to prevent top officials from seeking refuge behind delegations of responsibility and restrictions on the reporting upward of information that might trigger accountability.

CONCLUSION

For the reasons stated, it is respectfully submitted that the petition for a writ of certiorari should be granted.

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AUGUST 1974.

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[8] Such evidence may be considered under *United States* v. *Calderon*, 348 U.S. 160, which held that "reviewing courts * * * can seek corroborative evidence in the proof of both parties where, as in this case, the defendant introduces evidence in his own behalf after his motion for acquittal has been overruled." *Id.* at 164. See also *id.* at 164, n. 1.

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 73–1953

UNITED STATES OF AMERICA, APPELLEE

v.

JOHN R. PARK, APPELLANT

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND, AT BALTIMORE, JOSEPH H. YOUNG, DISTRICT JUDGE.

Argued November 7, 1973—Decided July 2, 1974

Before BOREMAN, Senior Circuit Judge, and CRAVEN and FIELD, Circuit Judges

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Gregory M. Harvey (*J. Cookman Boyd, Jr., Rob Ross Hendrickson* on brief) for Appellant; *Leonard M. Linton, Jr.*, Assistant United States Attorney, (*George Beall*, United States Attorney, on brief) for Appellee.

BOREMAN, Senior Circuit Judge:

John R. Park, President of Acme Markets, Inc. (hereafter Acme), was tried and convicted by a jury of violating 21 U.S.C. § 331(k)—causing the adultera-

tion of food which had traveled in interstate commerce and which was held for sale.[1] The evidence is undisputed that an inspector of the Food and Drug Administration (F.D.A.) made an inspection of Acme's Baltimore warehouse in November and December of 1971 and again in March of 1972. On both of these occasions the inspector found evidence of rodent infestation of food stored in the warehouse. As a result of these inspections an informal hearing was held in June 1972 at the F.D.A.'s Baltimore office. Although Park was not present, he was invited to attend the hearing and was represented by Robert W. McCahan, Baltimore Divisional Vice President of Acme.

In March of 1973, a five-count information was filed charging Acme *and* Park with the offenses cited above; four counts stemmed from the 1971 inspection and the fifth count from the 1972 inspection. Prior to trial Acme pleaded guilty to all counts. Park was tried on the theory that he "was a corporate officer who, under law, bore a relationship to the receipt and storage of food which would subject him to criminal liability under *United States* v. *Dotterweich,* 320 U.S. 277 (1943)." The jury found Park guilty on all counts and he was fined a total of $250.[2]

[1] 21 U.S.C. § 331 provides, in part: "The following acts and the causing thereof are prohibited:

* * * * *

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

[2] Park stated that a controlling factor in his decision to appeal this conviction was the fact that a second conviction under 21 U.S.C. § 331 is a felony, punishable by a term of imprisonment up to three years. Although violations of food and drug laws are punishable without regard to proof of scienter, the Supreme Court has indicated that it is an open question whether, in the absence of proof of scienter, an accused could be *incarcerated* for violating a "regulatory" statute. *Morissette* v. *United States*, 342 U.S. 246 (1952); *see also United States* v. *International Minerals & Chemical Corp.*, 402 U.S. 558, 564 (1971). We note that due process standards with respect to the loss of liberty appear to be higher than those with respect to loss of property. *Cf. Argersinger* v. *Hamlin*, 407 U.S. 25 (1972). We, too, consider this to be an open question and intimate no opinion on it.

Park appeals his conviction alleging (1) the court erred in its instructions to the jury and (2) prejudicial evidence of warnings of alleged prior violations of the Act was improperly admitted.

The court charged the jury that the sole question was "whether the Defendant held a position of authority and responsibility in the business of Acme Markets"; that Park could be found guilty "even if he did not consciously do wrong" and even though he had not "personally participated in the situation" if it were proved beyond a reasonable doubt that Park "had a responsible relation to the sitaution." We conclude that this charge does not correctly state the law of the case, that the conviction of Park on all counts must be reversed and a new trial awarded.

The Government asserts that this case is controlled by the decision of the Supreme Court in *United States* v. *Dotterweich,* 320 U.S. 277 (1943),[3] and contends

[3] As *Dotterweich* was postured when it reached the Supreme Court the primary question was whether "only the corporation was the 'person' subject to prosecution" under the Act. Therefore, the Supreme Court's opinion reveals very little about the factual setting in that case. Mr. Dotterweich was President and General Manager of Buffalo Pharmacal Company, Inc. The company was small, employing only twenty-six employees, all of whom worked on one upper floor of the building. Mr. Dotter-

that *Dotterweich* specifically held that the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. §§ 301–392, "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing." 320 U.S. at 281. From this the Government argues that the conviction may be predicated solely upon a showing that the defendant, Park, was the President of the offending corporation. The error here is that the Government has confused the element of "awareness of wrongdoing" with the element of "wrongful action";[4] *Dotterweich* dispenses with the need to prove the first of those elements but not the second.

As a general proposition, some act of commission or omission is an essential element of every crime. For an accused individual to be convicted it must be proved that he was in some way personally responsible for the act constituting the crime. The Supreme Court recognized this in *Dotterweich*: "The offense is committed * * * by all who do have such a responsible

weich was responsible for "general overseeing" of the Company operations; he was the direct supervisor of all employees. The trial transcript establishes that Mr. Dotterweich personally made every executive decision and had direct personal supervisory responsibility over the physical acts which resulted in the interstate shipment of misbranded and adulterated drugs. In the instant case Park is the chief executive officer of Acme, a multistate corporation giant. *See* note 5, *infra*. It is clear that his supervisory responsibility over most of the employees is indirect. There is no allegation or proof that Park was responsible for the executive decisions which resulted in contamination of the food. The facts of *Dotterweich* established the personal responsibility which we find lacking in the case before us.

[4] The Federal Food, Drug, and Cosmetic Act § 331(k) prohibits "causing" the adulteration of food which has traveled in interstate commerce and is held for sale. We would define "wrongful action" in this context as acts of the accused which *cause* the adulteration of such food.

share in the furtherance of the transaction which the statute outlaws * * *" 320 U.S. at 284. The criminal acts which were the subject of Acme's conviction cannot be charged to Park without proof that he participated directly or constructively therein or that the acts were done to further some criminal conspiracy in which he took part.[5] To use the language of *Dotterweich,* "under § 301 [21 U.S.C. § 331] a corporation may commit an offense and all persons who *aid and abet* its commission are equally guilty." 320 U.S. 284 (emphasis added). It is the defendant's relation to the criminal acts, not merely his relation to the corporation, which the jury must consider; 21 U.S.C. § 331 is concerned with criminal conduct and not proprietary relationships.

In sum, the court told the jury that Park would be guilty if it were shown that he "had a position of authority and responsibility in the situation out of which these charges arose." This instruction, taken in combination with the other parts of the charge related above, might well have left the jury with the erroneous impression that Park could be found guilty in the absence of "wrongful action" on his part.

Upon a subsequent trial the jury should be instructed that a finding of guilt must be predicated

[5] Acme maintained its principal corporate offices and headquarters in Philadelphia, Pennsylvania. As president, Park also maintained principal executive offices there. As Acme's president and chief executive officer, Park was theoretically in charge of approximately 36,000 employees in 874 retail outlets, 12 main warehouses and 4 special warehouses located on the east and west coasts of the United States. To hold Park *criminally* liable for the wrongful actions of each and every one of these employees by merely showing his position with the corporation is manifestly unjust, unfair and beyond the realm of reasonableness.

upon some wrongful action by Park. That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would "cause"[6] the contamination of the food.[7] "Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance." *Dotterweich, supra,* 320 U.S. at 284.

It is argued by the prosecution that the requirement of such proof will make enforcement more difficult. Nevertheless, the requirements of due process are intended to favor fairness and justice over ease of enforcement. We perceive nothing harsh about requiring proof of personal wrongdoing before sanctioning the imposition of criminal penalties.

We find another ground for reversal of Park's conviction. He contends that the admission in evidence of a warning by F.D.A. as to conditions alleged to have existed in 1970 in Acme's Philadelphia warehouse was prejudicial error requiring reversal. There was no evidence of prosecution of either Acme or Park following F.D.A.'s warning. In the recent case of *United States* v. *Woods*, 484 F. 2d 127 (4 Cir. 1973), this court examined in detail the admissibility of evidence relating to prior alleged offenses *not the subject*

[6] See note 4, *supra.*

[7] It would appear that the question of causation will be a principal issue upon a retrial. The question of causation is to be distinguished from that of intent. *United States* v. *Sheridan*, 329 U.S. 379 (1946). Some guidance with respect to the question of causation can be found in cases construing "aid and abet" which phrase appears in *United States* v. *Dotterweich*, 320 U.S. 277, 284 (1943). *See also United States* v. *Peoni*, 100 F. 2d 401 (2 Cir. 1938).

of conviction and we will not attempt to elaborate here.[8]

The *Woods* majority adopted a modern and liberal approach concerning the admissibility of such evidence. This court refused to decide the issue by "pigeonholing" the evidence under one of a number of recognized exceptions to the general rule that such evidence is inadmissible. Opting for a more flexible balancing test the court cited McCormick on Evidence § 190, p. 453 (Cleary Ed. 1972).

> "[T]he problem is not merely one of pigeonholing, but one of balancing, on the one side, the actual *need* for the other crimes evidence *in the light of the issues* and the other evidence available to the prosecution, the convincingness of the evidence that the other crimes were committed and that the accused was the actor, and the strength or weakness of the other crimes evidence in supporting the issue, and on the other, the degree to which the jury will probably be roused by the evidence to overmastering hostility." *United States* v. *Woods*, 484 F. 2d 127, 134 (4 Cir. 1973) (emphasis added).

In determining the admissibility of "prior crimes" evidence the *Woods* majority balanced the relevancy, persuasiveness and *need* for such evidence against the prejudice resulting to the defendant because of its admission. In a dissenting opinion in *Woods* Judge Widener favored the application of a traditional and

[8] In the case of *United States* v. *Woods*, *supra*, the defendant was convicted of first-degree murder of an eight-month-old infant. At trial evidence that other children in defendant's care had died or suffered respiratory difficulties was admitted to prove the commission of the crime charged. On appeal this court held that the evidence was admissible in general and also admissible to prove corpus delicti. Although *Woods* was decided in a completely different factual setting, the legal principles enunciated therein are clearly applicable to the present case.

less liberal balancing test.[9] Regardless of the balancing test applied, we are convinced that the evidence concerning the Philadelphia incident was inadmissible under the theory on which the case was tried.

Initially we conclude that there was no actual need for the Philadelphia evidence. In his jury charge the district judge stated that:

> "[Y]ou need not concern yourselves with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets."

Thus, as this case was submitted to the jury and in light of the sole issue presented, *need* for the Philadelphia evidence is not apparent. Absent a showing of such need we are of the opinion that, even under the liberal balancing test of *Woods,* the prejudicial effect of this evidence outweighed any possible relevancy or persuasiveness it might have had.[10]

---

[9] "In applying a balancing test, the considerations confronting the district court may be summarized succinctly: assuming an exception to the rule is applicable, before admitting evidence of prior acts or crimes, the court should determine, first, whether the evidence is relevant; secondly, whether the evidence is unduly prejudicial notwithstanding its relevancy; and, thirdly, having met both prior tests, whether the evidence is truly needed by the prosecution." *United States* v. *Woods*, 484 F. 2d 127, 141 (4 Cir. 1973) (Widener, J., dissenting opinion).

[10] Such a conclusion is consistent with the result reached in *Woods*. Throughout the opinion in *Woods* the court emphasized the overriding *need* for "prior crimes" evidence because of the particular and peculiar nature of infanticide cases. "Indeed, the evidence is so persuasive and *so necessary* in case of infanticide * * * if the wrongdoer is to be apprehended, that we think that its relevance clearly outweighs its prejudicial effect on the jury." *United States* v. *Woods*, 484 F. 2d 127, 135 (4 Cir. 1973) (emphasis added).

We note in passing, without deciding, that in light of our comments above evidence of "prior crimes" might become sufficiently necessary and relevant to warrant its admission on retrial. Our conclusion that the prosecution must show some wrongful act by the accused may effect the result of the balancing test as prescribed in *Woods* by increasing the *need* for "prior crimes" evidence. Whether the need for and the persuasiveness and relevance of such evidence may outweight its prejudicial effect will, in large part, depend on the prosecution's new approach to the presentation of its case. Thus, on retrial, it will be incumbent upon the district court to determine the admissibility of this "prior crime" evidence in light of developments.

Reversed and remanded for a new trial.

CRAVEN, Circuit Judge, dissenting:

I would affirm because I believe this case is controlled by *United States* v. *Dotterweich,* 320 U.S. 277 (1943). To express my viewpoint, it is enough to quote from Mr. Justice Frankfurther writing for the Court in *Dotterweich*:

> The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. . . . The prosecution to which Dotterweich was subjected is based on a now familiar

> type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger * * *. And so it is clear that shipments like those now in issue are "punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all * * *."

Id. at 280–81 (citations omitted).

In *Dotterweich* the Supreme Court reversed a Second Circuit decision that was said to be motivated by "fear that an enforcement of § 301(a) as written might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment." 320 U.S. at 284. But defendant Park was not just "remotely entangled" in the proscribed adulteration. Like Dotterweich, he was president of the corporation with full power to control its operations and to take measures to prevent rat infestation of food. Although he had delegated the day-to-day supervision of sanitation to subordinates, Park retained both the power and responsibility to see that the system of rodent control was effective, and if it didn't work, to change it.

As Mr. Justice Frankfurter said about Dotterweich:

> "The offense is committed * * * by all who * * * have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs [or food]. Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing

> be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

Id. at 284–85.

The trial judge made it perfectly clear to the jury that "the fact that the Defendant is present and is a chief executive officer of the Acme Markets does not require a finding of guilt. Though, he need not have personally participated in the situation, he must have had a responsible relationship to the issue. The issue is, in this case, whether the defendant, John R. Park, by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose."

Thus, again in the language of Mr. Justice Frankfurter, "the District Court properly left the question of the responsibility of [Park] for the shipment to the jury, and there was sufficient evidence to support its verdict." 320 U.S. at 285.

Moreover it is clear from examining the prosecutor's argument to the jury that there was no effort to equate the presidency of the corporation with the responsibility. Instead, the government argued that Mr. Park was responsible because he had established a system of rodent control that did not work in March 1970, November 1971 and March 1972 and that even so he made no effort to change or improve the system.[11]

[11] Park's testimony indicated the system was established before he became president, but he conceded that if it didn't work, and needed changing, it was his responsibility to change it. In addition, Park acknowledged having received a letter from the FDA in 1970 outlining unsanitary conditions an inspection team had found in the Philadelphia warehouse.

The government's contention was not that the jury should convict if they found that Mr. Park was president (that was undisputed) but that they should convict if they found it to be his responsibility for setting up a system of sanitation and of delegating responsibility in a way that does the job in a sanitary way.

I am sympathetic with my brothers' sense of justice that prompts them, it seems to me, to write into the statute some small degree of mens rea or scienter as a prerequisite to liability, but I share the government's fear that today's decision will undermine the congressional purpose of protecting "the innocent public who are wholly helpless" to protect themselves from contaminated food.

Because there will be a new trial, I want to align myself with the majority's suggestion that evidence in the nature of "prior offenses" may be admissible. Indeed, I would go further. If an additional burden of proof is to be put upon the government to show that Mr. Park acted wrongfully, then it would seem to me that evidence would clearly be admissible that Park's system of rodent control did not work in March 1970 in Philadelphia, or in November 1971 or March 1972 in Baltimore. If the rule is otherwise, I think the government cannot possibly sustain its new burden.

APPENDIX B

JUDGMENT

United States Court of Appeals for the Fourth Circuit

No. 73-1953

UNITED STATES OF AMERICA, APPELLEE

v.

JOHN R. PARK, APPELLANT

Appeal from the United States District Court for the District of Maryland

This cause came on to be heard on the record from the United States District Court for the District of Maryland, and was argued by counsel.

On consideration whereof, It is now here ordered and adjudged by this Court that the judgment of the said District Court appealed from, in this cause, be, and the same is hereby, reversed. The case is remanded to the United States District Court for the District of Maryland, at Baltimore, for a new trial, consistent with the opinion of the Court filed herewith.

WILLIAM K. SLATE, II,
Clerk.

A True Copy, Teste:

WILLIAM K. SLATE, II,
Clerk,
By WILMA UPSHUR, *Deputy Clerk.*

U.S. GOVERNMENT PRINTING OFFICE: 197

APPENDIX

Supreme Court, U. S.
FILED
DEC. 27 1974
MICHAEL RODAK, JR.

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-215

UNITED STATES OF AMERICA,
Petitioner,

v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI FILED AUGUST 30, 1974
CERTIORARI GRANTED NOVEMBER 11, 1974

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-215

UNITED STATES OF AMERICA,
Petitioner,

v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE FOURTH CIRCUIT

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IN THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 73-1953

UNITED STATES OF AMERICA, APPELLEE

v.

JOHN R. PARK, APPELLANT

DOCKET ENTRIES

DATE	FILINGS—PROCEEDINGS
8/ 2/73	Record on appeal in one volume filed, and appeal docketed.
8/ 2/73	Transcript of proceedings on May 9, 1973, in one volume; on May 10, 1973, in one volume; on May 25, 1973, in one volume; and on July 5, 1973, in one volume, filed. (All contained in one envelope)
8/ 2/73	Exhibits in one envelope received from the clerk of the district court at Baltimore, Md.
8/ 2/73	Briefing schedule established.
8/ 9/73	Appearance for appellee filed and entered.
8/10/73	Appearance for the appellant filed and entered.
9/10/73	Appellant's motion to defer preparation of the appendix pursuant to Rule 30(c) of the Federal Rules of Appellate Procedure, filed.
9/10/73	Order allowing appellant to defer preparation of the appendix pursuant to Rule 30(c), FRAP, filed.
9/12/73	One typewritten brief for appellant, filed.
9/12/73	Appellant's designation of portions of the record below and other items to be printed in the appendix, filed.

DATE	FILINGS—PROCEEDINGS
10/ 9/73	Notice of oral argument mailed. to Linton, Byrd, and Hendrickson.
10/12/73	Twenty-five (25) copies of the appellee's brief filed.
10/23/73	Four (4) copies of the appellant's Jt. appendix filed.
10/24/73	Forty (40) copies of the appellant's Jt. appendix filed.
10/25/73	Twenty-five (25) copies of the appellant's brief filed.
10/30/73	Twenty-five (25) copies of the appellant's reply brief filed.
11/ 7/73	Cause argued before Boreman, Senior Circuit Judge, Craven and Field, Circuit Judges, and submitted.
11/12/73	Appearance for the appellant filed and entered.
11/19/73	Record on appeal in one volume, transcripts of proceedings in four volumes, and exhibits in one envelope mailed to Judge Boreman.
7/ 2/74	Opinion filed. (HSB) JBC dissenting. (vsl)
7/ 2/74	Opinion mailed to counsel of record and the Clerk of the District Court at Baltimore, Maryland. (vsl)
7/ 2/74	Judgment of the District Court reversed; case remanded for a new trial. Judgment filed. (vsl)
7/ 8/74	Record on appeal in above received from Judge Boreman. dhb
7/23/74	Certified copy of the judgment and printed copy of the opinion transmitted to the Clerk of the District Court at Baltimore, Maryland.
7/23/74	Appellee's motion to stay mandate for 30 days pending application for certiorari filed. (foc)

DATE	FILINGS—PROCEEDINGS
7/23/74	Order granting appellee's motion to stay mandate for 30 days pending application for certiorari filed. (foc)
7/23/74	Copy of order to stay mandate for 30 days pending application for certiorari transmitted to Judges Boreman, Craven and Field. (foc)
9/ 9/74	Notice evidencing the filing petition for writ of certiorari in the Supreme Court September 6, 1974 filed. (No. 74-215) (Layne)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Criminal No. 73-0129

(Violation of Food, Drug and Cosmetic Act,
21 U.S.C. §§ 331 & 333)

UNITED STATES OF AMERICA

v.

ACME MARKETS, INC., a corporation;
and JOHN R. PARK, an individual

The United States Attorney for the District of Maryland charges:

That Acme Markets, Inc., a corporation, organized and existing under the laws of the State of Delaware, and trading and doing business at 2120 West Lafayette Avenue, Baltimore, Maryland, and John R. Park, an individual, at the time hereinafter mentioned President of said corporation, the defendants herein, did, within the District of Maryland, on or about August 5, 1971, receive a number of boxes of gelatin dessert, a food, which said food had been shipped in interstate commerce from Newark, Delaware.

That thereafter, within the period from on or about August 5, 1971, to on or about November 30, 1971, and while said food was being held for sale after shipment in interstate commerce as aforesaid, the said defendants did, at Baltimore, Maryland, within the District of Maryland,

cause a number of boxes of said food to be held in a building that was accessible to rodents, and did cause said food to be exposed to contamination by rodents.

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid resulted in said food being adulterated within the meaning of 21 U.S.C. § 342(a)(3), in that it consisted in part of a filthy substance by reason of the presence in said food of rodent pellets, rodent hairs, and by reason of being rodent gnawed;

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, resulted in said food being further adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that said food was held under insanitary conditions whereby it may have become contaminated with filth;

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, was an act caused to be done by said defendants, while said food was being held for sale after shipment in interstate commerce, which resulted in said food being adulterated as aforesaid in violation of Title 21 U.S.C. § 331(k).

21 U.S.C. § 331

COUNT II

The United States Attorney for the District of Maryland further charges:

That Acme Markets, Inc., a corporation, organized and existing under the laws of the State of Delaware, and trading and doing business at 2120 West Lafayette Avenue, Baltimore, Maryland, and John R. Park, an individual, at the time hereinafter mentioned President of said corporation, the defendants herein, did, within the District of Maryland, on or about November 3, 1971, receive a number of bags of flour, a food, which said food had been shipped in interstate commerce from Buffalo, New York.

That, thereafter, within the period from on or about November 3, 1971, to on or about December 1, 1971, and

while said food was being held for sale after shipment in interstate commerce as aforesaid, the said defendants did, at Baltimore, Maryland, within the District of Maryland, cause a number of bags of said food to be held in a ing that was accessible to rodents, and did cause said food to be exposed to contamination by rodents.

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, resulted in said food being adulterated within the meaning of 21 U.S.C. § 342(a)(3), in that it consisted in part of a filthy substance by reason of the presence in said food of rodent pellets, and by reason of being rodent gnawed;

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, resulted in said food being further adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that said food was held under insanitary conditions whereby it may have become contaminated with filth;

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid was an act caused to be done by said defendants, while said food was being held for sale after shipment in interstate commerce, which resulted in said food being adulterated as aforesaid in violation of Title 21 U.S.C. § 331(k).

21 U.S.C. § 331

COUNT III

The United States Attorney for the District of Maryland further charges:

That Acme Markets, Inc., a corporation, organized and existing under the laws of the State of Delaware, and trading and doing business at 2120 West Lafayette Avenue, Baltimore, Maryland, and John R. Park, an individual, at the time hereinafter mentioned President of said corporation, the defendants herein, did, within the District of Maryland, on or about November 4, 1971, receive a number of bags of flour, a food, which said food

had been shipped in interstate commerce from Buffalo, New York.

That thereafter, within the period from on or about November 4, 1971, to on or about December 1, 1971, and while said food was being held for sale after shipment in interstate commerce as aforesaid, the said defendants did, at Baltimore, Maryland, within the District of Maryland, cause a number of bags of said food to be held in a building that was accessible to rodents, and did cause said food to be exposed to contamination by rodents.

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, resulted in said food being adultered within the meaning of 21 U.S.C. § 342(a)(3), in that it consisted in part of a filthy substance by reason of the presence in said food of rodent pellets, rodent hairs, rodent nesting materials, and by reason of being rodent gnawed;

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, resulted in said food being further adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that said food was held under insanitary conditions whereby it may have become contaminated with filth;

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, was an act caused to be done by said defendants, while said food was being held for sale after shipment in interstate commerce, which resulted in said food being adulterated as aforesaid in violation of Title 21 U.S.C. § 331(k).

21 U.S.C. § 331

COUNT IV

The United States Attorney for the District of Maryland further charges:

That Acme Markets, Inc., a corporation, organized and existing under the laws of the State of Delaware, and trading and doing business at 2120 West Lafayette Avenue, Baltimore, Maryland, and John R. Park, an individual, at the time hereinafter mentioned President of said

corporation, the defendants herein, did, within the District of Maryland, on or about November 5, 1971, receive a number of bags of flour, a food, which said food had been shipped in interstate commerce from Lincoln, Nebraska.

That thereafter, within the period from on or about November 5, 1971, to on or about December 2, 1971, and while said food was being held for sale after shipment in interstate commerce as aforesaid, the said defendants did, at Baltimore, Maryland, within the District of Maryland, cause a number of bags of said food to be held in a building that was accessible to rodents, and did cause said food to be exposed to contamination by rodents.

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, resulted in said food being adulterated within the meaning of 21 U.S.C. §342(a)(3), in that it consisted in part of a filthy substance by reason of the presence in said food of rodent pellets, and by reason of being rodent gnawed;

That said act of causing of said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, resulted in said food being further adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that said food was held under insanitary conditions whereby it may have become contaminated with filth;

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, was an act caused to be done by said defendants, while said food was being held for sale after shipment in interstate commerce, which resulted in said food being adulterated as aforesaid in violation of Title 21 U.S.C. § 331(k).

21 U.S.C. § 331

COUNT V

The United States Attorney for the District of Maryland further charges:

That Acme Markets, Inc., a corporation, organized and existing under the laws of the State of Delaware, and

trading and doing business at 2120 West Lafayette Avenue, Baltimore, Maryland, and John R. Park, an individual, at the time hereinafter mentioned President of said corporation, the defendants herein, did, within the District of Maryland, on or about January 11, 1972, receive a number of bags of flour, a food, which said food had been shipped in interstate commerce from Buffalo, New York.

That thereafter, within the period from on or about January 11, 1972, to on or about March 14, 1972, and while said food was being held for sale after shipment in interstate commerce as aforesaid, the said defendants did, at Baltimore, Maryland, within the District of Maryland, cause a number of bags of said food to be held in a building that was accessible to rodents, and did cause said food to be exposed to contamination by rodents.

That said act of causing of said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, resulted in said food being adulterated within the meaning of 21 U.S.C. § 342(a)(3), in that it consisted in part of a filthy substance by reason of being rodent gnawed;

That said act of causing of said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, resulted in said food being further adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that said food was held under insanitary conditions whereby it may have become contaminated with filth;

That said act of causing said food to be held in said building as aforesaid and to be exposed to contamination as aforesaid, was an act caused to be done by said defendants, while said food was being held for sale after shipment in interstate commerce, which resulted in said food being adulterated as aforesaid in violation of Title 21 U.S.C. § 331(k).

21 U.S.C. § 331

GEORGE BEALL
United States Attorney

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Criminal No. 73-0129

UNITED STATES OF AMERICA

v.

ACME MARKETS, INC., a corporation;
and JOHN R. PARK, an individual

MOTION FOR BILL OF PARTICULARS

The Defendant, John R. Park, moves for a Bill of Particulars of the Information in the above case, as follows:

As to Count I

1. Is it intended to be alleged that the Defendant personally received the gelatin desert mentioned in Count I of the Information?
2. If not, in exactly what manner did this Defendant participate in the receipt of said gelatin desert?
3. Is it intended to be alleged that this Defendant personally caused a number of boxes of said gelatin desert to be held in a building that was accessible to rodents?
4. If not, in exactly what manner did this Defendant cause the said boxes of said gelatin desert to be held in a building that was accessible to rodents?
5. Is it intended to be alleged that this Defendant personally caused said gelatin desert to be exposed to contamination by rodents?
6. If not, in exactly what manner did this Defendant cause said food to be exposed to contamination by rodents?

As to Count II

7. Is it intended to be alleged that this Defendant personally received the number of bags of flour mentioned in Count II of the Information?
8. If not, exactly what manner did this Defendant participate in the receipt of said bags of flour?
9. Is it intended to be alleged that this Defendant personally caused a number of bags of flour to be held in a building that was accessible to rodents?
10. If not, in exactly what manner did this Defendant cause the said bags of flour to be held in a building that was accessible to rodents?
11. Is it intended to be alleged that this Defendant personally caused said bags of flour to be exposed to contamination by rodents?
12. If not, in exactly what manner did this Defendant cause said bags of flour to be exposed to contamination by rodents?

As to Count III

13. Is it intended to be alleged that this Defendant personally received the number of bags of flour mentioned in Count III of the Information?
14. If not, in exactly what manner did this Defendant participate in the receipt of said bags of flour?
15. Is it intended to be alleged that this Defendant personally caused a number of bags of flour to be held in a building that was accessible to rodents?
16. If not, in exactly what manner did this Defendant cause the said bags of flour to be held in a building that was accessible to rodents?
17. Is it intended to be alleged that this Defendant personally caused said bags of flour to be exposed to contamination by rodents?
18. If not, in exactly what manner did this Defendant cause said bags of flour to be exposed to contamination by rodents?

As to Count IV

19. Is it intended to be alleged that this Defendant personally received the number of bags of flour mentioned in Count IV of the Information?

20. If not, in exactly what manner did this Defendant participate in the receipt of said bags of flour?

21. Is it intended to be alleged that this Defendant personally caused a number of bags of flour to be held in a building that was accessible to rodents?

22. If not, in exactly what manner did this Defendant cause the said bags of flour to be held in a building that was accessible to rodents?

23. Is it intended to be alleged that this Defendant personally caused said bags of flour to be exposed to contamination by rodents?

24. If not, in exactly what manner did this Defendant cause said bags of flour to be exposed to contamination by rodents?

As to Count V

25. Is it intended to be alleged that this Defendant personally received the number of bags of flour mentioned in Count V of the Information?

26. If not, in exactly what manner did this Defendant participate in the receipt of said bags of flour.

27. Is it intended to be alleged that this Defendant personally caused a number of bags of flour to be held in a building that was accessible to rodents?

28. If not, in exactly what manner did this Defendant cause the said bags of flour to be held in a building that was accessible to rodents?

29. Is it intended to be alleged that this Defendant personally caused said bags of flour to be exposed to contamination by rodents?

30. If not, in exactly what manner did this Defendant cause said bags of flour to be exposed to contamination by rodents?

/s/

/s/

/s/

Attorneys for Defendant,
John R. Park

I HEREBY CERTIFY that the within Motion for Bill of Particulars was served upon the United States of America by mailing a copy thereof to Hon. George Beall, United States Attorney for the District of Maryland, to the attention of Leonard M. Linton, Jr., Esq., Assistant United States Attorney, Post Office Building, Baltimore, Maryland 21202, this 6th day of April, 1973.

/s/

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Criminal No. 73-0129

UNITED STATES OF AMERICA

v.

ACME MARKETS, INC., a corporation;
and JOHN R. PARK, an individual

ANSWER TO MOTION FOR BILL OF PARTICULARS

The Government opposes the motion for a bill of particulars as follows:

1. The request for a bill of particulars by the defendant is an attempt by the defendant to compel the disclosure of the Government's evidence in advance of trial or, alternatively, to inquire into the Government's legal theory of the case in advance of trial. A bill of particulars is not a device by which the defendant may compel disclosure of the Government's evidence in advance of trial. *See* United States v. Crisona, 271 F.Supp. 150 (S.D.N.Y. 1967), *aff'd.*, 416 F.2d 107 (2nd Cir. 1969). Similarly, inquiry into the Government's legal theory is not a proper purpose for a bill of particulars. *See* United States v. Verra, 203 F.Supp. 87, 92 (S.D.N.Y. 1962).

2. As a matter of discovery and not as a matter subject to particularization, the Government is willing to disclose that its evidence will not show that the defendant personally performed the acts of receiving the foods described in the various counts of the indictment of causing them to be held in a building that was accessible to

rodents and of causing them to be exposed to contamination by rodents. The Government's evidence will simply show that the defendant was a corporate officer who, under law, bore a relationship to the receipt and storage of the food which would subject him to criminal liability under *United States* v. *Dotterweich*, 320 U.S. 277 (1943).

/s/ George Beall
United States Attorney

/s/ Leonard M. Linton, Jr.
Assistant United States Attorney

[Certificate of Service omitted in printing]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

[Title omitted in printing]

TRANSCRIPT OF PROCEEDINGS HELD BEFORE
THE HONORABLE JOSEPH H. YOUNG
ON MAY 9 AND MAY 10, 1973

* * * *

(2) [The Court] First, I would advise you that this is a criminal case that comes before you by reason of an Information. It is a five count Information filed in March of this year, charging the Defendants, Acme Markets, Inc. and John R. Park, president and chief executive officer (3) of Acme Markets, Inc., with violations of certain provisions of the Federal Food, Drug and Cosmetic Act.

The Defendants are charged with violation of Title 21 of the United States Code, Section 331, and the provison thereof, for having caused certain lots of food to become adulterated by holding it in a building where it could be exposed or contaminated while being held for sale after shipment in interstate commerce.

I have read this to you, so the questions I ask of you will have some more meaning for you.

The Defendant, the corporation, as well as the individual, have filed a plea of not guilty to the Information and, therefore, raise issues of facts to be tried by a jury.

* * * *

(4) First, as indicated, the Defendants are Acme Markets, Inc., and John R. Park, who is an officer of that organization. Is Mr. Park in the courtroom?

* * * *

(16) Also, in the voir dire proceedings, I indicated to the panel that the case was against Acme Markets, Inc. and John R. Park, individually. Following this conference at the bench, I will advise the jury that I misspoke the title of the case. The case is actually a proceeding against

John R. Park, as an individual, as president of Acme Markets, Inc.

Further, I think, Mr. Pierson, you have something (17) you want to put on the record, is that correct?

(Mr. Pierson) In view of the fact that Acme Market is pleading guilty, we object to the introduction of any factual evidence, particularly relating to the substance of the offenses, unless the Government says that it can and does, in point of fact, follow this up by evidence which would link Mr. Park with the commission of these offense indirectly.

(The Court) Any comments, Mr. Linton?

(Mr. Linton) Yes, Your Honor. I am not sure what he means by "indirectly." It seems to me that is the whole question in this case.

(The Court) I am not sure what he means by it. Obviously, I will have to handle it as it comes up.

You are giving this caveat to the Government? You are going to object to certain testimony if it is introduced?

(Mr. Pierson) I don't want to object to each thing, each picture and the description.

(The Court) You want to enter an objection now to be a standing objection to any testimony by way of—

(Mr. Pierson) If you take it, it should be subject to the exception, subject to follow-up.

(The Court) I will grant you the right to have a standing objection without standing up and raising it (18) each time; however, I am going to allow it to come in, subject, of course, to your exception and not necessarily to the follow-up by the Government. I will have to rule on that when the time comes, because I am not at all sure that it is necessary.

You have your objection, Mr. Pierson.

* * * *

(19) (The Court) Members of the panel, in giving you the cases and the parties, I misspoke the parties who are involved. The case is actually going to trial only as to

the Defendant, John R. Park, who is an officer of Acme Markets, Inc.

Very well.

* * * *

(30) [Mr. Linton] Finally, the Government will establish that Mr. John R. Park, the Defendant on trial here, is the president of Acme Foods. That after this rodent condition was permitted to exist, Mr. John R. Park was told that this condition existed. An inspector of the Food and Drug (31) Administration who visited the warehouse left a list of observations with his employees in the warehouse, but beyond that, he left the general list of the observations and findings he made in the course of the inspection. Mr. John R. Park personally had a letter telling him of these problems. But, then, in spite of that letter, in January of 1972, in March of 1972, again, the Food and Drug Administration inspector goes to the Acme warehouse at 2120 West Lafayette Avenue and, again, having warned the employees of the plant as to what the conditions were that existed, Mr. Park having been told of the conditions that existed in the warehouse in January, in March of 1972, again, the inspector finds not only rodent contamination, but, again, an instance of rodents gnawing into consumer packages within the warehouse. That is in March.

* * * *

(33) Then, we will put on evidence to show that in January of 1971, Mr. John R. Park, president of the corporation, was mailed a letter telling him of this problem, that he responded to the letter, and that as of March of 1971, the conditions persisted.

* * * *

(38) THEREUPON—

GORDEN K. BROWN,

was called as a witness for and on behalf of the Government, and, having been first duly sworn, testified as follows:

* * * *

(40) DIRECT EXAMINATION

By Mr. Linton:

* * * *

Q. On November 29th, December 3rd, December 6th through 10th, December 13th, and December 14th, did you, in the course of your duties, inspect the Acme Markets, Incorporated warehouse, located at 2120 West Lafayette Avenue in Baltimore, Maryland? A. Yes, I did.

Q. Was there any other person present with you at the time of that inspection? A. Yes, Inspector James Merrick.

Q. Would you please tell us what took place upon your arrival at the Acme Markets on November 29th, sir? A. We stopped at the guard house on the front of the building and then were directed to Mr. William Scarzinski, supervisor in the warehouse.

Q. After introducing yourself, what did you do? A. We issued a notice of inspection and identified ourselves and told Mr. Scarzinski we went there to make an inspection and we proceeded to inspect the warehouse.

Q. Would you describe the warehouse complex, if you please, sir? (41) A. It is a rather large complex involving an older building, adjoined by a newer building and a smaller building across the alley. The older building is three stories high with a basement. On one end, there is a five-story bakery, also owned by the firm. At the other end is a large, one-story newer building, and at the back, on the back side of both the older section and the newer section are railroad sidings, and on the front side there is a loading area dock for trucks. Across from this same loading area is a smaller, older building.

Q. How long did your inspection last in November and December? A. Twelve days.

Q. Did you make a report of that inspection, sir? A. Yes, I did.

Q. When did you make that report, sir? A. Immediately following the completion of the inspection.

Q. Was it delivered to anyone, sir? A. It was turned into our supervisor at our district office.

Q. And was a report of what you found given to any employees of Acme? A. Yes, we issued a list of observations at the completion of the inspection.

(42) Q. What is a list of observations, sir? A. This is a list of the objectionable conditions encountered during the inspections, which we are required to issue at the completion of the inspection. This is a requirement of the Food, Drug and Cosmetic Act.

Q. To whom was it delivered, sir? A. It was delivered to Mr. Zahn.

Q. Who is Mr. Zahn, sir? A. He is the manager of the warehouse that we were inspecting.

Q. Now, I show you a document and ask you if you can recognize it, sir? A. Yes, sir, I do.

Q. What is it, sir? A. It is a list of the observations we issued to Mr. Zahn.

Q. How do you recognize it, sir? A. Well, it has my name on the bottom of it. I signed my name and it has the name of the firm, the date, and has Mr. Zahn's name and title at the top.

Q. What do you put in a list of observations, sir? A. We put in the observations of things we see during the inspection which are considered to be, based on our experience, objectionable and also objectionable in the (43) standpoint that they may involve a violation of the Food, Drug and Cosmetic Act or the products stored therein have been held under unsanitary conditions.

Q. Your report is then broken down to the various sections of the observations of the warehouse, is that correct? A. Yes.

Q. What, in the course of your inspections, did you observe in the section which is described as the basement? A. We found extensive evidence of rodent infestation in the form of rat and mouse pellets throughout the entire perimeter area and along the wall.

We also found that the doors leading to the basement area from the rail siding had openings at the bottom or openings beneath part of the door that came down at the bottom large enough to admit rodent entry. There were

also roden pellets found on a number of different packages of boxes of various items stored in the basement, and looking at this document, I see there were also broken windows along the rail siding.

Q. You say the document serves to refresh your recollection? A. Yes.

Q. Of those items? (44) A. Yes.

Q. Continue. A. There was rodent nesting material found in and around boxes of paper bags. There are a number of other specific items listed here—altogether twelve items listed in the basement.

* * * *

(47) Q. I show you Government's Exhibits (G) and (H), which is a notation listed under the pallet board which is not rodent-proof, and the pallet board against the door, which is not rodent-proof. The photograph portrays a forklift pallet laying against the side of the warehouse.

What is not rodent-proof about that, sir? A. The rail siding, where this pallet board is located, is badly littered with trash and debris and the pallet board leans up against the wall built between the ground level where the railroad tracks are and almost up to the edge of the door in the basement. The door, in turn, then, has an opening beneath it large enough to admit rodents.

Q. What does the pallet serve to do? What is the significance of the pallet? A. It gives a stairway or a ladder, if you will, up to the ledge where the rodents could enter the building.

Q. It gives who a stairway, sir? (48) A. The rodents.

* * * *

Q. I hand you Government's Exhibit No. 4 and ask you to review the portion which refers to the "first floor, old building," and relate generally what your investigation of the first floor of the old building revealed, sir. A. There are five items listed on here. The first one includes "Liquid Plumber," which is a drainage cleaner and was stored on the ledge in the hanging meat room near a cooked ham.

Q. What is the significance of "Liquid Plumber" drainage cleaner? A. It would be a hazardous type of material to be around a food product.

Q. Why so? A. Where it might fall on the product and contaminate (49) it with a harmful material.

Q. What other observations did you make, sir? A. Thirty mouse pellets on the floor along walls and on the ledge in the hanging meat room. There were at least twenty mouse pellets beside bales of lime Jello and one of the bales had a chewed rodent hole in the product. We also saw two hundred mouse pellets in the perimeter area of the Jello storage area. There were several hundred rat and mouse pellets along walls and in corners and on pallets of wild bird food.

* * * *

(66) Q. Besides what you have described there, what else did you observe in the course of your first inspection of November and December of 1971, sir? A. Well, there was extensive rodent evidence throughout the first floor area and there were rodent entry openings around many of the doors. The warehouse itself was extremely overcrowded. There were indications of improper or inadequate stock rotations where we found fresh merchandise stacked in front of older lots. The firm marks the lots as they are received with a sticker with a date on it, and we found in some cases that there were lots (67) that were several months old in the back with fresh merchandise stacked in front. This would indicate inadequate rotation of stock. There were—

(Mr. Pierson) Objected to and move to strike.

(The Court) Motion granted. The jury will disregard the last testimony of the witness.

By Mr. Linton:

Q. What is the significance of the stock rotation and sanitation, sir?

(Mr. Pierson) Objected to.

(The Court) Sustained.

(Mr. Linton) May I be heard and place my position on the record, Your Honor?

(The Court) You may at a later time.

(Mr. Linton) Beg your pardon?

(The Court) You may at the proper time.

(Mr. Linton) Thank you, Your Honor.

* * * *

Q. Did there come a subsequent time when you returned to the Acme warehouse? A. Yes, I did.

(68) Q. When was that, sir? A. In March of 1972.

Q. Mr. Brown, I show you a document and ask you whether you can recognize it, sir? A. Yes, I do.

Q. What is it? A. It is a list of observations which I issued to Mr. Zahn at the completion of the second inspection in March.

* * * *

(70) Q. What did you observe in the course of your second inspection, sir? A. We found that there had been a great deal of effort made in the way of cleaning up the warehouse, reducing the total inventory and in rodent-proofing measures. We also found there was still evidence of rodent activity in the building and in the warehouses and we found some rodent-contaminated lots of food items.

* * * *

(77) Q. After you had given your list of observations to Mr. Zahn in March of 1972—and to whom did you give them in November or December of 1971? A. It was issued to Mr. Zahn on both inspections in the presence of other gentlemen.

Q. Besides simply issuing them the list of observations, did you do anything else with respect to (78) management? A. Which inspection are you referring to, or are you referring to both of them?

Q. Either or both. A. Of course, we discussed the items listed in great detail and they were warned about the significance of the objectionable conditions and told that some of the things that would be needed to correct the situation, such as rodent-proofing measures and reducing the amount of the stock that was causing the overcrowded condition, and of course, bringing to their attention the fact that the spilled food items and the trash,

and such, provides rodent harbingers and attract rodents and make a place for them to live.

Q. Were these discussed with anyone besides Mr. Zahn? A. Yes, they were.

Q. With whom else? A. With Mr. McCahan, the local manager of the entire Acme operation here in this area.

Q. How do you spell his last name, sir? A. I think it is capital M-c capital C-a-h-a-n, I believe.

Q. Who is he, sir? A. He is the vice-president in charge of the (79) district office of the company.

Q. Anyone else, sir? A. Yes, Mr. William Bronsdon, the head sanitation engineer from the firm's Philadelphia office was present. Mr. William Scarzinski was present during the—I beleive he was present during the first discussion, either during the inspection and possibly at the final discussion. There were several other gentlemen present during these discussions.

Q. Do you know their names, sir? A. Mr. Thomas Alwein, who was present during part of these discussions.

Q. Do you know what his job is, sir? A. After the first inspection, he was appointed as a sanitarian in the warehouse under the direction of Mr. Zahn.

Q. Anyone else you recall being present? A. Well, there were other people present during parts of the inspections. I don't have anything before me which would show who all was present at which particular time.

Q. Do you recall any of those people, in particular, any names of any of those people? A. Mr. Zahn, the warehouse manager, which was the man I was issuing the paper to, was present at both times. (80) There was also a Mr. Hugo Hinckel and Mr. Tom Kelly present during parts of both of those inspections.

Q. Who are they, sir? A. They are also sanitation people working under Mr. Bronsdon.

Q. Do you recall any other corporate employees or officers being present, either at the conference following the submission of the list of the observations, or during any of the inspections? A. There was a Mr. St. John,

a vice-president in charge of warehousing was down, I believe, during the first inspection.

Q. When you say you believe he was there, do you recall, sir? A. He was there part of one day, as I recall, on the first inspection, the November and December inspections.

(The Court) Anything else, Mr. Linton?

(Mr. Linton) I don't believe so. If I may just have a second, Your Honor.

By Mr. Linton:

Q. In addition to discussing the conditions that you found in the warehouse, did you offer them any assistance, sir, or give them any advice? A. Well, during the inspection when the objectionable conditions were encountered, of course they (81) were pointed out to whichever of these gentlemen happened to be accompanying me at the time and also during the first inspection, I provided them with copies of a pamphlet, which is prepared by the Food and Drug Administration, on good principles of food sanitation. As I recall, I also provided them with copies of the Food and Drug Administration Act, and also in the discussions that would develop, some of the measures that needed to be taken to correct the situation were discussed at considerable length throughout both inspections.

Q. Was a pamphlet given on the first occasion, during the first inspection? A. Yes.

Q. On both the first and second? A. Yes.

Q. Was a copy of the law given to them during the first inspection as well? A. Yes.

* * * *

(82) CROSS EXAMINATION

By Mr. Pierson:

Q. This is a rather large warehouse, isn't it? A. Yes, it is.

Q. Would you say 250,000 square feet would be a fair estimate? A. I believe it is a little larger.

Q. It took you twelve days to make your full examination? A. That is right.

Q. And in the course of this examination, there (83) were some items, I assume, that you found on the second go-around in March that you did not notice on the first inspection—for example, the rusted door where a rodent could get in? You didn't remark on that in your first inspection, did you? A. No, I didn't. The interior was blocking it.

Q. It was there, though wasn't it? A. Yes, presumably.

Q. But you didn't notice it the first time? A. No.

Q. But you remarked on it the second time, did you not? A. That is right.

* * * *

Q. Now, in your meetings with people in this warehouse, did you run into someone by the name of Laucht? A. Yes, I did.

Q. He was the manager in charge of sanitation for the Baltimore area, do you recall that? If you don't know, just say so. A. Yes, I recall that he was introduced as that earlier.

Q. Then there was a warehousing manager, Mr. Zahn? (84) A. Do you mean was he present?

Q. At that time, the warehousing manager was Mr. Zahn, is that correct? A. Yes.

Q. And you also had dealings with Mr. McCahan, who was the head of the Baltimore district? A. That is correct.

Q. This facility, this warehouse, as far as you know, is the only Acme warehouse in the Baltimore district, is that correct? A. To the best of my knowledge, yes.

Q. Do you know approximately how many stores Acme had in this district at that time? A. Just from information supplied by members—

Q. It was over a hundred, wasn't it? A. I believe that is correct, yes.

Q. Right, and then isn't it a fact that on the first occasion that you met Mr. Bronsdon, isn't it a fact that he came in while the inspection was going on? A. Mr.

Brondson, to the best of memory, came in on the second day of the first inspection and was only on hand the last day during the final discussions on the second inspection, if my memory serves me correctly.

Q. But he was there during part of the first inspection? (85) A. Most of it.

Q. Apparently he had been alerted by somebody that this was going on and came down. A. That is correct.

Q. From their headquarters in Philadelphia? A. That is correct.

Q. And his job, if you know, was head of sanitation for the whole Acme chain, isn't that right? A. That is what I was informed, yes.

Q. In that job, he had certain assistants, but mainly, he was responsible for the sanitation in the chain. Is that what he told you? A. What?

Q. What impression did you get? A. My impression was he was responsible for inspecting for sanitation.

Q. In other words, the sanitation which should have been done by the people in Baltimore, but it was his job to go around and see it was done, in a sense, like yourself, but on the side of the company. A. I would say—all I know about it, as far as his responsibilities were concerned, is that he was making inspections again similar to ours for sanitation purposes.

Q. And he participated, in a sense, of being there almost all of the first inspection? (86) A. That is correct.

Q. And learned what you felt had to be done. You discussed this, did you? A. We discussed it thoroughly, yes.

Q. They didn't make any effort to keep you from making the inspection, did they? A. No, none whatsoever.

Q. Would it be fair to say that they cooperated with you very fully, as far as you making your inspection? A. That is correct.

* * * *

Q. And isn't it a fact, Mr. Brown, that in every instance where you pointed out rodent infestation or pos-

sible rodent infestation or broken bags or rodent urine or pellets, that all of that material was destroyed voluntarily by Acme? A. Yes, that is correct.

Q. How was that done? A. That was done under our supervision.

Q. Under the supervision of the Food and Drug (87) Administration? A. The Food and Drug Administration by hauling it to the dump and burying it.

Q. They did that voluntarily, didn't they? A. That is correct.

* * * *

Q. Isn't it a fact that in many instances, there might only be one bag which was subject to rodent (88) contamination or exposed to it and, yet, the whole bale was destroyed? Isn't that right? A. That is essentially correct. The pellets would be on the interior.

Q. There was no effort to open this bale and to see if we had ten good ones and ten bad ones? The whole twenty would have to go? A. Right.

Q. And it is also true, is it not, that that didn't only apply to the bales. They destroyed not only the one bale, but every bale that was on a particular pallet where rodent infestation manifested itself? A. With a few exceptions, yet.

Q. So a great deal of material was destroyed which might possibly have been salvaged? A. That is correct.

* * * *

(90) Did you make any effort to add up the figures to see how much food was destroyed? A. I believe the figure, totaling all lots destroyed on the first inspection, was approximately 153,000 pounds. I don't know the value.

Q. Well, would the figure of $15,000 ring a bell with you?

* * * *

A. I think the figures on here were my figures.

* * * *

(91) Q. Getting back to something that you said late in your direct examination, while you were not satisfied with what had been done between the first and second

inspections, a great deal had been done, had it not? A. Yes, it had.

REDIRECT EXAMINATION

By Mr. Linton:

* * * *

(93) A. I didn't find any specific lots of food items that had been chewed into and defiled by rats. The defilement that I found and that I saw was confined to mouse infestation.

* * * *

(95) Q. Did Mr. Bronsdon ever indicate to you that he had authority to do any more than make inspections, sir? A. Other than making the inspections and making recommendations about what was needed to correct them, I don't recall that he did.

* * * *

RECROSS EXAMINATION

By Mr. Pierson:

Q. Mr. Brown, Mr. McCahan was the man in charge of the Baltimore district, isn't that right? A. He was identified as such.

Q. Wouldn't he be the man to whom Mr. Bronsdon would make his recommendations? A. If I recall correctly, Mr. Bronsdon told me that he made his recommendations, at times, to him, also to (96) Mr. Zahn and to his own immediate supervisor, whom I believe is Mr. Fahlhaber in the Philadelphia office.

* * * *

(112) THEREUPON—

NORMAN KRAMER,

was called as a witness for and on behalf of the Government, and, having been first duly sworn, testified as follows:

* * * *

DIRECT EXAMINATION

By Mr. Linton:

* * * *

(113) Q. Mr. Kramer, I hand you a letter and ask you whether you can recognize it, sir? A. Yes I do.

(114) Q. What is it, sir? A. This is what is commonly known as a regulatory letter.

Q. Commonly known to whom? A. In the Food and Drug Administration, principally.

Q. What is a regulatory letter? A. A regulatory letter is a letter which is issued, sent to a firm, which sets the administrative review or conclusions based upon some evidence at hand which needs some correction.

Q. Who makes the decision to write such letters, sir? A. I make that decision.

Q. Did you make that decision in this instance, sir? A. Yes, I did.

Q. It is a letter from whom to whom? A. This letter is addressed to John R. Park, president of Acme Markets, Incorporated, 124 North 15th Street, Philadelphia, Pennsylvania. It is signed by myself, Norman Kramer, Food and Drug Officer, Baltimore, Maryland.

Q. When is it dated? A. It is dated January 27th, 1972.

Q. Was that, in fact, the date that the letter was sent, sir? (115) A. Either on that date or about. I see by receipt, which is certified mail, it was mailed on the same date.

Q. You referred to a receipt for certified mail. To what are you referring? A. I am referring to the fact that this letter goes by certified mail, and I have before me a receipt for certified mail number 105337, and another card indicating instructions to delivery employee, which is a receipt on the other end acknowledging receipt of this letter.

(Mr. Pierson) By whom?

(The Court) Pardon?

(Mr. Linton) It speaks for itself, Your Honor. Mr. Pierson can get into by whom it was signed on cross examination.

(The Court) So, are you objecting?

(Mr. Pierson) He didn't finish. He says it is acknowledging receipt of the letter.

(The Witness) The signature of the addressee is Acme Markets, and I cannot read the name underneath it. It looks like William something or other, William Egoff. I don't recognize the name.

(Mr. Linton) I ask that the letter and the receipt for certified mail and instructions to the delivering employee be admitted as Government's Exhibit No. 23.

* * * *

(116) (The Witness) The purpose of this letter and this type of letter is to advise—

(The Court) No so much this type. This letter is what we are talking about.

(The Witness) I am sorry, Your Honor.

The purpose of sending this letter is to advise the corporate officials that we feel should be advised of a serious problem that we have encountered in one of their establishments, warehouse, factories, or what (117) have you; the purpose being to give them some opportunity to know of the administrative decision and to, hopefully, for the firm to take measures to correct the serious conditions that are set forth in the letter.

By Mr. Linton:

Q. Did you get a response from Mr. Park when you wrote the letter, sir? A. No, I didn't. From Mr. Park, no, I didn't.

Q. Did you get any response at all to your letter, sir? A. Yes, I did.

Q. In what form did that response come, sir? A. I received a letter from Mr. McCahan.

Q. I hand you a letter and ask you whether you recognize it, sir? A. Yes, I do.

Q. What is it, sir? A. This is a four-page letter in response to my letter of January 27th. This letter is

dated February 7th, 1972, and is signed by R. W. McCahan.

* * * *

(119) CROSS EXAMINATION

By Mr. Pierson:

* * * *

Q. Have you had any contact with Mr. McCahan?
(120) A. Yes, sir.

Q. And Mr. McCahan is the man in charge of the Baltimore district of Acme, or was? A. I think he had been introduced to me as a divisional head of Baltimore.

Q. As a matter of fact, in your original letter, you sent a copy to Mr. McCahan, didn't you? A. Yes, I did, for courtesy purposes and to let everybody know.

Q. He was directly in charge of the Baltimore operation, isn't that correct? That is why you wrote him, isn't it? A. Wrote to whom?

Q. Yes. A. I wrote to Mr. Park.

Q. That is why you wrote a copy to Mr. McCahan, isn't that right? A. Yes.

Q. You did that because you knew he was in charge of the Baltimore operation? A. I knew that he was, in part, in charge of the operation.

Q. What do you mean "in part?" A. That he was a division head.

Q. That he was a division head. (121) A. Yes.

Q. And that made him in charge of the Baltimore operation A. Right. I wasn't aware that he was in charge of all of the things that had to be pointed out, and I wanted to make certain that everyone was aware of the problems we encountered during these two inspections.

Q. And you didn't think that he was in charge of the sanitary measures or requirements? A. I really don't know exactly what you mean by "in charge." I think he was a divisional head.

Q. Right, and he had charge of the warehouse and the stores. You knew that, didn't you? A Right, yes.

Q. And as far as sanitation is concerned, you knew he was in charge of that, also, didn't you? A. Well, I knew he was an individual who had some responsibility in the area, but I wanted to be certain that the most responsible people in the corporation were aware of the problem which was, at that time, regarded as a very serious problem.

Q. Yes, but you knew that anything that was done in the Baltimore district would be done under Mr. McCahan's direction or supervision, didn't you? A. No, not completely so.

(122) Q. What did you think his job was? A. A division head of the Baltimore district office.

Q. What did that mean to you A. Well, it meant that someone had appointed him, delegated certain responsibilities involving the Baltimore warehouse.

Q. Overall responsibility. A. I didn't know exactly.

Q. But you knew that he was the head man of the Baltimore operation, didn't you? A. One of the head men of this operation.

Q. Give me the name of another one? A. Mr. Park. Mr. Park and Mr. Fahlhaber. There was a number of vice-presidents that I was told had different functions.

Q. Right, and you knew that Mr. McCahan's function was to run the Baltimore operation, didn't you? A. In part.

Q. Okay. What do you mean by "in part?" A. I don't know how much. I knew he was, in part, because in conversations with him and reviewing reports of the problem, it appeared to me that there were areas required of other people elsewhere, particularly in the Philadelphia office. I was given such names as Mr. Hammel, Mr. Fahlhaber, (123) and a few others, depending upon specific problems.

Q. Had you ever heard of Mr. Bronsdon? A. Yes, Mr. Bronsdon.

Q. And didn't you know that Mr. Bronsdon was directly in charge of sanitation for Acme? A. I knew he was very active in this field and was making inspections of all the warehouses in this part of the country, as I understand it, of course, for Acme Markets.

Q. So, essentially what he was doing for Acme was the same thing your agents were doing for you, isn't that right? A. I believe so.

(Mr. Pierson) No further questions.

(The Court) Anything else?

REDIRECT EXAMINATION

By Mr. Linton:

Q. Was there some question as to the extent of Mr. McCahan's authority when you wrote him that letter? A. I didn't write him that letter. I wrote the letter to Mr. Park, with a copy to Mr. McCahan.

Q. When you addressed that copy to Mr. McCahan, did you know the full extent of Mr. McCahan's authority? A. To Mr. McCahan's authority?

Q. Yes. A. I assessed in my own mind what his full authority (124) was.

Q. What was that assessment, sir? A. That he was head of this Baltimore section, which included the warehouse operation. As to what degree of responsibility he had, I wasn't certain.

* * * *

Thereupon—

ROBERT W. McCAHAN

was called as a witness for and on behalf of the Government, and, having been first duly sworn, testified as follows:

* * * *

DIRECT EXAMINATION

By Mr. Linton:

Q. Mr. McCahan, what is your job title and where are you employed, sir? A. My job title is Division Vice-President. I am employed by Acme Markets, and I am in charge of the Baltimore division for Acme Markets.

Q. Within the geographical area for which you are (125) responsible, is this warehouse located at 2120 West Lafayette, Baltimore, Maryland, within your district, sir? A. Yes, sir and it is in my responsibility.

Q. I show you a letter presently marked Government's Exhibit No. 24 and ask you whether you recognize the letter sir? A. Yes, I do.

Q. Did you write the letter, sir? A. Yes, I did.

Q. Did you write it on your own behalf or did you write it on behalf of someone else? A. I wrote it on behalf of the company and Mr. Park, as stated in the letter.

Q. Did he approve the letter before you mailed it, sir? A. That, I cannot tell. I worked through our general counsel, Mr. Gilfillan, on this.

* * * *

(127) CROSS EXAMINATION

By Mr. Pierson:

* * * *

Q. Now, at the time of the episode which is complained of in the Information, how many warehouses did Acme have in the Baltimore division? A. To the best of my knowledge, only one warehouse.

* * * *

A. Approximately one hundred and twenty or one hundred and twenty-five.

* * * *

(128) A. My duties and responsibilities encompassed responsibility for the operation of all the stores and warehouses and bakeries within the jurisdiction of division six within our company, which is the Baltimore division.

Q. Did you have any duties with reference to sanitation? A Yes, sir.

(129) Q. What were they? A. My duties with regard to sanitation would apply to, again, all of the facilities in the division, and it would be to keep the premises sanitary and clean and to operate within the law.

Q. What measures did you take? Did you have anybody working under you who has something to do with sanitation, directly? A. Yes, sir. At the time I took

the office as division manager, and ever since then, we have had a man whose prime responsibility is sanitation inspections and quality control in the division and he reports to me.

Q. He reports to you? A. Yes, sir.

Q. Now, in addition to this man, did you have any help? Did you employ any outside persons in connection with sanitation at the warehouse? A. Yes, sir.

Q. Whom? A. We employed—and don't hold me to this exactly—but I believe it was Hygienic Sanitation Company.

Q. In Baltimore? A. Yes, I believe.

Q. What were they supposed to do? (130) A. It was their role, as I understand it in their contract with our company, to keep all of our facilities free and clear of vermin and rodents.

Q. Were they under contract with you in November of '71 and March of '72 when the inspection was made by the Food and Drug Administration? A. To the best of my knowledge, they were, yes, sir.

Q. Were you present when the inspection took place? I am speaking of the first inspection A. No, sir, I was not.

Q. Do you know Mr. Bronsdon? A. Yes, I do.

Q. Was he with the company at that time? A. Yes, he was.

Q. What was his duty at that time or his responsibility? A. Mr. Bronsdon is sanitary inspection engineer. I hope I have got his title right. He is employed by our company and operates out of the corporate engineering department in Philadelphia, and it is his function to help the divisions and to oversee the sanitation programs in the divisions of the company, the various divisions of the company, this being only one.

Q. Is it his responsibility to make recommendations on what has to be done? (131) A. Yes, sir.

Q. Have you had any contact with Mr. Bronsdon in connection with these matters? A. Yes,sir, I have had considerable contact with Mr. Bronsdon, and we have taken immediate action on all of the recommendations.

* * * *

(132) Q. Did you know, in point of fact, that not enough had been done to satisfy the Food and Drug Administration—that is, after the first inspection? A. No, sir.

Q. When did you find that out? A. I became aware of that as the result of the second inspection.

Q. Which was in March of '72? A. Yes, sir.

Q. What did you do then? A. I made an all-out drive to marshal every force that was at my command to get in compliance immediately.

Q. Have they been back since, to your knowledge? A. To the best of my knowledge, there has been no inspection by the Food and Drug Administration of our warehouse since that day; however, I believe there had been Food and Drug Administration officials there from time to time, which is their normal course, to pick up samples of merchandise.

(133) Q. Now with respect to material that is contaminated, what is your policy? A. Our policy with regard to contaminated material is that it should be discarded and never placed in a position where it might even be remotely offered for sale.

* * * *

Do you have any standing instructions as to what is to be done with that material if it has been discovered to have been contaminated in some way? A. Yes, sir.

Q. What is that? A. It is to be destroyed.

Q. Is it destroyed at the store? A. It is destroyed at the store level, yes, sir.

* * * *

(134) Q. Who authorizes destruction? A. Our warehouse supervisors.

Q. Ultimately, who is the final authority in the Baltimore district? A. With regard to whether or not merchandise be destroyed?

Q. Right. Would he have ultimate authority there? A. He would have ultimate authority, I believe.

Q. You wouldn't be involved in that? A. If you mean, would he call me up or write me or ask me for permission to destroy a pallet of Gold Medal flour, or some-

thing like that, why, no. He would do that on his own authority.

Q. Did you or did you not make an effort to comply with the requirements of the Food and Drug Administration after the first inspection? A. We made a very strong and concerted effort to comply one hundred per cent with the rules and regulations, as set forth, and as we understood them from the Food and Drug Administration.

Q. How much did you spend, approximately? A. Including the aforementioned cost of merchandise, (135) which represented the initial amount of merchandise that was destroyed, I believe it was close to $70,000 or $69,000 and some cents.

This included the cost of new doors, rodent-proofing the building, the cost of brand new automatic sweeping equipment, the hiring of ten additional people whose duties were solely that of cleaning, and a supervisor to supervise them. Those are the things that stand out in my mind.

Q. Do you still have a sanitation man in your organization? A. Yes, sir.

Q. Is it still the same person? A. Yes, sir.

Q. Do or do you not still have an outside service? A. Yes, sir, we do.

Q. With whom do you deal? A. Now, there, you have got me, because we have changed. To the best of my knowledge, we have a new company which is doing the outside sanitation work for us, and I just can't remember the name of the company. I am sorry. I am sure Mr. Bronsdon would know.

* * * *

(136) REDIRECT EXAMINATION

By Mr. Linton:

* * * *

A. If I said that Mr. Bronsdon reports to me, I used the wrong phrase. He would report to me on things that relate to my division and would aid me in a staff capacity.

Q. Under whose authority did he act? A. He acted

under the authority of his superior at corporate headquarters, who is our vice-president of engineering, Mr. Albert Fahlhaber.

* * * *

(137) Q. And would reports that go to you go to Mr. Fahlhaber as well, sir? A. What kind of reports?

Q. Reports as to sanitary conditions or sanitation problems in the warehouses? A. I don't think so. I think that they would be more likely to go—for example, a report that would come to me, I would go to Mr. Bronsdon on it. I called Mr. Fahlhaber on this particular incident myself and brought his attention to it.

* * * *

Q. Could he have, on his own authority, destroyed 150,000 pounds of food, sir. A. At one fell swoop?

Q. At one fell swoop sir. (138) A. I think he would have contacted me before he did it.

* * * *

(139) Thereupon—

A. E. GILFILLAN

was called as a witness for an on behalf of the Government, and, having been first duly sworn according to law, was examined and testified as follows:

* * * *

(140) DIRECT EXAMINATION

By Mr. Linton:

* * * *

Q. What are the duties of the preseident of the (141) corporation, sir? A. We have a bylaw that describes or prescribes the duties of the chief executive officer of the company, and if you wish, I would be glad to read it to you.

Q. If you would, please, sir. A. Do you want to see it first?

Q. No, thank you. I assume it is all right. A. This is Bylaw number 29 and it is headed "The Chief Executive Officer of the Company: The Chairman of the board of directors or the president shall be the chief executive officer of the company as the board of directors may from time to time determine. He shall, subject to the board of directors, have general and active supervision of the affairs, business, offices and employees of the company. In the absence or inability to act, as chairman of the board, he shall preside over all meetings of the stockholders and of the board of directors and, by virtue of his office, shall be a member of all committees of the board of directors and of the company, except as otherwise specifically provided.

He shall, from time to time, in his discretion or at the order of the board, report the operations and affairs of the company. He shall also perform such other duties and have such other powers as may be assigned to him from time to time by the board of directors."

* * * *

(142) CROSS EXAMINATION

By Mr. Pierson:

* * * *

A. He functions by delegating the various activities of the corporation to those people who are in charge of it. If it is legal, it is delegated to me. If it is engineering, it is delegated to engineering. If it is real estate, it is delegated to real estate.

Q. How many employees does Acme Markets have? A. Approximately 36,000 employees.

Q. About how many stores does Acme have? A. Roughly, about a hundred stores, that includes stores on the West Coast of the subsidiary.

Q. Where are the locations of these stores, generally? A. The stores are located in New York, Pennsylvania, New Jersey, Delaware, Maryland, Virginia, West Virginia, and California. Then we have a packing plant in Lincoln, Nebraska, and we have a carrier in Hurlock,

Maryland, and we have some other activities around the country.

(143) Q. In connection with sanitation, under whose heading would that come? A. That comes under the vice-president of engineering and that is Albert J. Fahlhaber.

Q. Does he do this himself? A. No, he has a sanitation committee, headed by Mr. Bronsdon—B-r-o-n-s-d-o-n.

Q. And what are Mr. Bronsdon's duties? A. He has charge of sanitation in the stores, the warehouses, and he is under Mr. Fahlhaber but working in conjunction with the various division vice presidents, since we have about, I think, six or seven divisions.

* * * *

REDIRECT EXAMINATION

By Mr. Linton:

* * * *

(144) Q. Does he delegate all his authority? A. He obviously retains certain things, which are the big, broad, principles of the operation of the company, and he has the responsibility of seeing that they all work together.

Q. Normal day-to-day activities are the responsibilities of these persons to whom he delegates them, right? A. That is right. The normal operating duties. It would be physically impossible for him.

Q. Was the rodent infestation problem of the scope that was involved in the warehouse in Baltimore a normal day-to-day activity? A. Food warehouses do have those problems—how much of a day-to-day thing they are, I don't know—but they are something that comes along, and normally would come under the jurisdiction of the department of engineering and sanitation department.

* * * *

(148) (Mr. Pierson) The Government having rested, first, we would move that the testimony admitted to exception be stricken as not having been followed up.

(The Court) Motion denied.

(Mr. Pierson Secondly, we move for a judgment or acquittal on the grounds that the evidence in chief has shown that Mr. Park is not personally concerned in this Food and Drug violation. The chain of command has been shown, and it is certainly obvious from Mr. McCahan's testimony where the responsibility lay for complying with the Food and Drug Act.

(The Court) Dotterweich still seems to be the last word in this area.

(Mr. Pierson) I beg your pardon, Your Honor?

(The Court) Dotterweich still seems to be the last word in this area. Whatever I might think of it, it has not been changed by Congressional action. I assume that the Congress had not acted, knowing the results of that case. It seems to me that case would be controlling here and says, in effect, the ultimate judgment should rest with the jury. So, I will hear you again at the conclusion of the evidence, but at this time, I will deny the motion.

* * * *

(153) THEREUPON—

JOHN R. PARK

was called as a witness for and on his own behalf, and, having been first duly sworn, testified as follows:

* * * *

DIRECT EXAMINATION

By Mr. Pierson:

* * * *

(154) Q. How long have you been with that company? A. Since 1939.

Q. What was your first job? A. My first job was a clerk in a retail grocery store.

(155) Q. For the same company? A. Yes, for the same company. Then, it was the American Stores Company.

Q. Have you been with them ever since? A. Yes, I have.

* * * *

Q. Have you ever been convicted of any crime? A. No, sir.

Q. Have you ever been accused of one that you know of? A. No, sir.

Q. Mr. Park, how many employees does Acme Markets have? A. Approximately 35,000.

Q. And all of these are, in a sense, under your general direction, is that correct? A. That is right.

Q. How do you function? In other words, how does this operate? You certainly don't go to every store and sell bags of tea or sugar or things like that. What is the setup? In other words, do you have subordinates who do certain work? (156) A. Yes.

Q. Would you tell the Court and jury just in a general way what kind of chain of command there is. A. We are organized in the organizational structure for responsibilities for certain functions and phases of our operations are assigned to individuals who, in turn, have staff and departments under them. We have two executive vice-presidents of the company.

Q. What do they do? A. One is executive vice-president for the administrative functions of the company. The other executive vice-president is responsible for the sales and operations of the company. This is our eastern operation. We also have a West Coast subsidiary company, which is a separate corporation, and the president of that company has his own organization, and he is responsible directly to me for his operation in the West.

Then, in addition to the executive vice-presidents, there are vice-presidents who have assigned departmental responsibilities. We have the geographic regions and areas, of which Baltimore is one.

Q. I want to interrupt you at that point.

How many stores did Acme have in November of 1971 and March of 1972, just in a very rough way? A. I'm afraid I couldn't answer that accurately. I (157) can tell you that now we have approximately a few less than nine

hundred total stores, and at that time, I would say we had more stores than that.

Q. How many warehouses do you have? A. I believe we have thirteen warehouses.

Q. Do you have one in each region? A. We have one in each region. In the Philadelphia region, for example, we have three grocery food warehouses. We also have a general merchandise warehouse and a drug warehouse.

Q. Was Baltimore one of the regions in March of '72? A. We call it "divisions," but it is a geographic region, yes, sir.

Q. Who was in charge of that and what was his title? A. Robert McCahan, and he was Division Six vice-president.

Q. How many stores did he have under his jurisdiction, if you know? A. I don't know exactly, but I believe it was in the neighborhood of a hundred and ten to a hundred and twenty at that time.

Q. Now, Mr. Park, with reference to sanitation, which is the issue here, what provision was made to your (158) knowledge, to have a person or persons take care of that phase of your business.

First, let me withdraw that and ask you this. Did this come under one of the executive vice-presidents and, if so, which one? A. What do you mean?

Q. Just sanitation. A. Sanitation, the technical aspects of sanitation does come under a vice-president in charge of engineering. This is the technical side of it, the inspection aspect of it.

Q. When you say inspection, what was the purpose of the inspection? A. The inspection's purpose would be to see that our standards of sanitation and cleanliness are being maintained in all of our operations.

Q. You mean in stores and warehouses? A. Stores and warehouses, plants, and so forth.

Q. In 1971, did you have any person who was under the executive vice-president for engineering who was personally responsible for sanitation from an inspection point of view? A. I may have misled you. The man in charge of engineering, the gentleman in charge of engineering, is a vice-president. He is not an executive

vice-president, and, (159) yes, sir, he did have a man under him, Mr. William Bronsdon, who is in charge of the sanitation technical aspect and inspection aspect of our sanitation program.

Q. How long has Mr. Bronsdon been with Acme? A. I believe he was employed in 1965.

Q. Do you know how many people he had under him, from the standpoint of his own staff. I am not talking about the local sanitation people. I am talking about Mr. Bronsdon's staff. A. I don't know precisely. I believe Mr. Fahlhaber, to whom Mr. Bronsdon reports, feels that he had an adequate staff to perform his functions. It was several people.

Q. It was more than one man? A. I am quite sure of that, yes, sir.

Q. Do you know anything about Bronsdon's qualifications? A. Yes, when he was employed, Mr. Fahlhaber felt that he had an excellent background in this field of food sanitation, that his experience was such that he was well-qualified. I know he has a degree. I believe he has a Bachelor of Science Degree, I think in the dairy field, and he was well-recognized as being knowledgeable and capable in this area.

Q. To your knowledge, did he have any contact in his (160) capacity—not in connection with Acme, but as a sanitation expert—with the Food and Drug Administration of the United States? A. It is my impression that he has been recognized with a high degree of competency by members of the Food and Drug Administration. I think he has participated in discussions and seminars at their request. That is my impression, that he is well regarded.

(Mr. Pierson) Let me have this marked for identification as Defendant's Exhibit 1 for identification.

(Thereupon, a Workshop Program on Warehouse Sanitation in conjunction with the State of New York was marked as Defendant's Exhibit No. 1 for identification.)

By Mr. Pierson:

Q. Now, I show you Defendant's Exhibit 1 for identification and ask you if you can tell us what that is. A. This is a Food and Drug Administration Workshop Program on Warehouse Sanitation conducted by the Food and Drug Administration in cooperation with the State of New York.

Q. Does it show whether Mr. Bronsdon participated in this? (161) A. Yes, on the program agenda, in one of the morning sessions, Mr. Bronsdon is shown as, I would imagine he was the speaker on the subject of inventory control. He is listed in the summary as one of the speakers, in addition to being on the program.

* * * *

(162) Q. To your knowledge, is he, or was he not regarded as being an expert in this field? A. It is my impression that he was very highly regarded, professionally, and still is.

Q. How did you regard him? A. I regarded him in the same manner.

Q. Now, how did you learn about the problem in the (163) Baltimore warehouse? I am assuming you did learn of it? A. Yes, I did, sir.

I learned of it through the letter that was referred to yesterday, addressed to me, calling my attention to the problem that existed.

Q. That was Dr. Kramer's letter? A. Dr. Kramer's letter. I believe it was dated approximately the 29th of January, or thereabouts.

(The Court) It is Government's Exhibit 23, is that right?

(The Clerk) Yes, Your Honor.

(The Witness) The letter came in, and a copy of that letter was addressed and sent to Bob McCahan, as the man in charge of this division, and the original of the letter showed that a copy of it went to Mr. McCahan. I believe Bob McCahan received his copy ahead of the receipt of the original in my office, and when Mr. McCahan received his copy, he immediately got in touch with Mr. Gilfillan, who is the vice-president for legal

matters of our company, and told Mr. Gilfillan this letter had been received in his office and was on its way to my office. I believe, if my recollection is correct, Mr. Gilfillan came into my office and asked my secretary to let him see the letter immediately upon its receipt, and I believe that Mr. Gilfillan read the letter and got in touch with Mr. (164) McCahan at once, told him we had received it, and came back to me and discussed the letter with me.

* * * *

A. He told me that he had discussed the matter with Mr. McCahan and that Mr. McCahan was investigating the situation immediately and would be taking corrective action and would be preparing a summary of the corrective action to reply to the letter.

Q. Was that your normal procedure, or do you have many of these things? A. Well, no, we don't have many of these things, but I would say that Mr. Gilfillan and I worked very closely. He is in my office several times a day, usually, and any correspondence that has any legal aspect or relates to Government matters, Mr. Gilfillan is usually in on it very promptly.

Q. Well, aside from what you did, or aside from what Mr. Gilfillan did for you, what could you have done? Is there anything you could have done? A. I don't believe there was anything I could have done more constructively than what I found was being done.

Q. And you were satisfied with what was being done? (165) A. Yes, sir.

Q. Now, there are other problems arising in connection with the activities of your company, are there not? A. Yes, sir.

Q. And in a general rule, are they handled in the same manner by reference to high-level subordinates? A. Yes, sir.

Q. Could you, yourself, as head of a company with 35,000 employees, do all of this stuff yourself? A. No, sir.

Q. What is your duty, in general? In other words, you come into the office in the morning. What do you do? Do you just sit down and smoke a pipe?

(The Court) He is not a lawyer, Mr. Pierson.
(Mr. Pierson) I beg your pardon, Your Honor?
(The Court) He is not a lawyer.

(Laughter.)

(The Witness) Well, my days aren't always as orderly as I would like. I am responsible for the overall operation of the company. I have, I believe, presently, approximately thirteen of our key executives that report to me directly. We have a general schedule of meetings where they bring me up to date on their activities and we discuss their affairs and their problems. This takes (166) up a good bit of time each week.

* * * *

A. Yes, it is my understanding that under each division vice-president, they have the responsibility for the overall sanitation maintenance assigned to an individual.

* * * *

(167) (The Witness) Who was responsible for the Baltimore divisions?
(Mr. Pierson) Yes.
(The Witness) Mr. McCahan.

By Mr. Pierson:

Q. Would that include sanitation? A. Yes, sir.
(Mr. Pierson) Your witness.

CROSS EXAMINATION

By Mr. Linton:

Q. In fact, overall, in the whole corporation, sanitation is included in your responsibility, isn't it, sir? A. I am responsible for the activities and the affairs of the whole company.

Q. Including sanitation, sir? A. I am responsible for the company's operation in its entirety.

Q. Including sanitation or not including sanitation? A. Including everything.

Q. Including sanitation or not including sanitation? A. I believe I would have to answer yes. I think that

that is a thing that I am responsible for in the entire operation of the company.

Q. Well, that is the kind of responsibility (168) that you normally assign to subordinates who you supervise, is that correct, sir? A. That, along with the many other phases of our company, I have to assign to dependable subordinates.

Q. And those subordinates include a Mr. Albert Fahlhaber, the vice-president for engineering? A. Yes, sir.

Q. They include a divisional vice-president, Mr. McCahan?

Q. Do they include a man by the name of of Mr. St. John? A. Yes.

Q. Who is Mr. St. John? A. Mr. St. John is our director of our distribution services.

Q. What does that mean? What is his job? A. Well, his job is primarily supervising the distribution centers in our Philadelphia division. That is his day-to-day primary responsibility. He also, from time to time, because of the breadth of that responsibility, is available to assist the other divisions in some of these distribution center matters.

Q. Like Mr. St. John came down to Baltimore during the inspection of the Baltimore warehouse, didn't he? A. I understand he did.

(169) Q. Who is Mr. Hammel? A. Mr. Hammel is the executive vice-president of sales and operations. He is the man to whom Mr. McCahan reports directly.

Q. And Mr. Bronsdon, as well, falls under Mr. Fahlhaber's supervision, but through Mr. Fahlhaber you direct Mr. Bronsdon as well, is that correct? A. Yes, sir.

Q. How many warehouses does Acme operate, sir? A. I think I was asked earlier, and without counting them, I think it is in the neighborhood of thirteen or fourteen.

Q. Are they all the same size? A. No, there is quite a variation in size and nature.

Q. There are about eight major ones, as I understand it? A. There would be eight grocery warehouses in the East. We also have two major grocery warehouses in California.

Q. And as of 1970, I think March of 1970, Mr. Fahlhaber was at that time your divisional vice-president? A. Mr. Fahlhaber is in charge of engineering.

Q. I am sorry. Vice-president in charge of engineering as of March of 1970? (170) A. Yes, he was.

Q. And Mr. Bronsdon was sanitation engineer under his direction in March of 1970, sir? A. Yes.

(Mr. Pierson) I think you mean March of 1972.

(Mr. Linton) No, I mean March of 1970.

By Mr. Linton:

Q. And Mr. St. John was in his capacity handling warehousing matters in 1970, sir? A. Yes, sir.

Q. And was Mr. Hammel executive vice-president in March of 1970? A. I am not sure. Mr. Hammel was made executive vice-president, and I do not believe he was executive vice-president in March of 1970.

Q. Among the warehouses you had as of March, 1970, were warehouses in Philadelphia, is that not right, sir? A. Yes, sir.

Q. Who was the division vice-president of the Philadelphia warehouses, sir?

(Mr. Pierson) Your Honor, I object to that.

(The Court) How is it relevant?

(Mr. Linton) Pardon?

(The Court) How is it relevant?

(171) (Mr. Linton) It is relevant because there is—

(Mr. Pierson) Wait a minute. My suggestion is that we approach the bench.

(The Court) All right.

(Thereupon, an off-the-record discussion was held at the bench, out of the presence and hearing of the jury.)

(Thereupon, the following proceedings were had in open court, in the presence and hearing of the jury.)

(The Court) Was there an objection on that?

(Mr. Pierson) Yes, sir.

(The Court) Overruled.

By Mr. Linton:

Q. Do you recall who was the divisional vice-president for whatever division included the Philadelphia warehouse?

(The Court) We are talking, again, Mr. Park, about 1970.

(The Witness) The gentleman who is responsible for the Philadelphia division, did you say, sir?

(Mr. Linton) Yes, sir.

(The Witness) In March of 1970, I believe it (172) was not designated as a vice-president at that time. This is to the best of recollection of the timing of this, but this was a gentleman named Phillip Helmsby.

By Mr. Linton:

Q. And that is someone other than Mr. Robert McCahan, who was divisional vice-president of division five as of November of '71? A. In Philadelphia?

Q. Yes, sir. A. You mean Mr. Helmsby was different from Mr. McCahan?

Q. Yes. A. Yes, they are two different people.

Q. And as of March—

(Mr. Pierson) Your Honor, my objection goes to the entire line.

(The Court) Overruled.

By Mr. Linton:

Q. And as of the inspection of March 23rd—

(Mr. Boyd) Mr. Pierson asked if the objection goes to the entire line, Your Honor.

(The Court) You may have your objection to the entire line, but it is the same ruling.

By Mr. Linton:

Q. As of March 23rd to March 26th of 1970 at your (173) warehouse at 59th and Upland Way in Philadelphia, Pennsylvania, there was a rodent infestation problem there at that warehouse at the same time, wasn't there, sir? A. I can't recall that specific incident. There could have been.

Q. Mr. Park, I show you a letter and ask you whether you recognize it, sir? A. Well, I am not positive that

I recognize it, but it is addressed to Acme Markets, and it is addressed to John Park's attention, John Park, president, and I would believe that I had seen this. It does look familiar, yes, sir.

Q. Would you read the letter, sir, and would you indicate whether or not you recall having received the letter and whether you are familiar with the contents of the letter, sir? A. You wish me to read the entire letter?

Q. To yourself, please.

(Thereupon, a letter was handed to the witness, and the witness complied with the instructions of counsel.)

(The Witness) This letter is dated April 24th, 1970, and I believe I did read that letter at that time.

(Mr. Linton) I would ask that letter be (174) admitted in evidence as Government's Exhibit 27.

(Thereupon, a letter dated April 24th, 1970 to John R. Park, was admitted in evidence as Government's Exhibit No. 27.)

By Mr. Linton:

Q. Mr. Park, the letter that you have indicated that you believe you did read, indicates certain objectionable conditions in the establishment at 59th and Upland Way in Philadelphia, Pennsylvania, and it lists them, is that correct, sir? A. Yes, sir.

Q. And the objectionable conditions are enumerated, and the first is, sir, potential rodent entryway noted by an ill fitting door and doors in ill repair in southwest corner of warehouse, at dock at old salvage room and at receiving and shipping doors, which were observed to be open most of the time. Number two, rodent nesting, rodent excreta pellets, rodent staining on bale bagging and rodent gnawed holes were noted among bales of flour stored in the warehouse. Number three, potential rodent harborage was noted in discarded paper and sawdust and other debris piled up in corner of shipping and receiving dock in bakery and warehouse. Rodent excreta pellets

were observed among bags of sawdust (175) or wood shavings.

Is that a correct statement, sir, of the objectionable conditions listed in the letter, sir? A. I believe you read the letter as it is written.

Q. Now, those conditions existed in March of 1970 in a warehouse in Philadelphia, is that correct, sir?

(Mr. Pierson) Objection, sir. He did not say he knew anything about it. He said he got the letter. He didn't say that he knew they were there.

(The Court) I assume he wasn't aware of those conditions at the time, from what he has indicated, but he did receive a letter, and that was the reference in the letter.

By Mr. Linton:

Q. You were made aware of those facts or those statements in the letter, is that correct?

(Mr. Pierson) Objection.

(The Court) Overruled.

By Mr. Linton:

Q. You were aware of those statements in that letter—

(Mr. Pierson) Objection, repetitious.

(The Court) Overruled.

By Mr. Linton:

Q. You were aware of it? (176) A. I read the letter and would be aware of the contents.

Q. And this was at the same time that Mr. Bronsdon and Mr. Fahlhaber and the gentlemen who headed the Philadelphia warehouses were all under your direction and responsible for sanitation? A. In 1970, the situation you described—That is Mr. St. John, is the name of the gentleman you are referring to.

Q. And while you had delegated responsibilities for sanitation to those persons in March of 1970, apparently the job wasn't getting done.

(Mr. Pierson) Objected to, Your Honor, Argumentative.

(The Court) Sustained.

By Mr. Linton:

Q. In spite of their being delegated the responsibilities, you still received a letter complaining of conditions in the warehouse, didn't you?

(Mr. Pierson) Objection. The thing speaks for itself.

(The Court) Overruled.

(The Witness) Mr. St. John's responsibility was supervision of the operation of the warehouse, not just sanitation, sir.

(177) By Mr. Linton:

Q. But Mr. Fahlhaber and Mr. Bronsdon were supposed to be responsible for sanitation. A. Mr. Fahlhaber is responsible for all engineering of our company, and one of the gentlemen who reports to him is Mr. Bronsdon, who is responsible for sanitation and inspection.

Q. And this same set of persons, except that Mr. McCahan is the divisional vice-president, rather than Mr. Hammel up there, were responsible for seeing that the Baltimore warehouse was sanitary, isn't that correct?

(Mr. Pierson) Objection.

(The Court) Overruled.

(The Witness) Well, they are two entirely separate divisions.

By Mr. Linton:

Q. But Mr. Fahlhaber and Mr. Bronsdon were responsible in both divisions, and in one Mr. Hammel was and in one Mr. McCahan was, on a divisional level. A. Would you make that statement again?

Q. As to Philadelphia, Mr. Fahlhaber, Mr. Bronsdon, and your divisional man up there—although, they weren't a division at the time—Mr. St. John, were responsible for the sanitation up there in March of 1970. As of November of 1971, Mr. Fahlhaber, Mr. Bronsdon, in this case (178) a different divisional vice-president, Mr. McCahan, was responsible for sanitation in the Baltimore warehouse. A. Responsible for operations.

Q. And sanitation? A. To the extent that is included, sir, yes. I would like to just differentiate that their job is quite broad and complex.

Q. As is yours. A. Yes.

Q. And after the same problem occurred twice, once in Philadelphia and once in Baltimore, did you have any reason to believe that the system you had set up of handling sanitation, the responsibilities you had delegated to others for sanitation, that system just wasn't working, sir? A. Well, the fact that this occurrence occurred in Baltimore indicated that it wasn't working perfectly.

Q. If a system was set up and wasn't working, who was responsible for that, sir? A. In Baltimore, I would hold Mr. McCahan responsible.

Q. Who set up the system, sir? A. The organizational structure has been evolved over a good many years. Actually, I am responsible for the entire organizational structure.

(179) Q. And if a system that is set up and it doesn't work, you are responsible for changing it, is that correct? A. For any result which occurs in our company, I am ultimately the chief executive officer and, therefore, responsible.

(Mr. Linton) No further questions.

REDIRECT EXAMINATION

By Mr. Pierson:

Q. Mr. Park, do you know what happened as a result of the Philadelphia incident? Was there any prosecution of any kind? A. No, not to my knowledge.

Q. Were there any court proceedings of any kind? A. No, not to my knowledge.

Q. And were your people up there able to satisfy the Food and Drug Administration? A That is my impression.

Q. Nothing else ever came to your knowledge that anything in Philadelphia would affect the operation of the system anywhere else? A. That is right, sir. To

my knowledge, corrective action and immediate attention was given, as a result of the letter, in Philadelphia.

Q. And everybody was satisfied? (180) A. I think that is right, sir.

(Mr. Pierson) That is all.

RECROSS EXAMINATION

By Mr. Linton:

Q. How do you know that the Food and Drug Administration was satisfied, sir? A. Well, I have no reason to know that they weren't.

Q. The Food and Drug Administration did hold a hearing with some of your subordinates, did it not, in 1970, didn't it, sir, following this incident? A. I believe so.

Q. Did you attend that hearing, sir? A. No, sir.

Q. Did someone in your behalf attend the hearing, sir? A. I think that the individuals responsible for the operation of these facilities did. This is my impression. I can't recall specifically. If you have the record there, you would know.

(Mr. Linton) No further questions.

REDIRECT EXAMINATION

By Mr. Pierson:

Q. After the Philadelphia episode and the hearing, did you ever get any letter from the Food and Drug Administration saying that they were, in any way, (181) dissatisfied with what had taken place? I am talking about after this hearing. A. I don't recall any, Mr. Pierson.

Q. Did anybody in your organization or from the Food and Drug Administration get in touch with you and say that the result of what had been done was unsatisfactory? A. No, sir.

(Mr. Pierson) That is all.

RECROSS EXAMINATION

By Mr. Linton:

Q. Well, you do stand before the jury as a criminal Defendant today, don't you?

(Mr. Pierson) Now, what was that for?

(The Court) I don't know. Do you object?

(Mr. Pierson) Certainly I object.

(The Court) Sustained.

(Mr. Linton) No further questions.

(The Court) Anything else?

(Mr. Pierson) If you want to know whether he is the Defendant, I am willing to stipulate that he is the Defendant.

(The Court) I will take judicial notice of that. Anything else, gentlemen?

(Mr. Pierson) No, Your Honor.

* * * *

(182) Your Honor, I want to renew our motion for judgment of acquittal at the end of the entire case.

(The Court) Very well. Motion is denied.

* * * *

(194) [Closing argument] (Mr. Linton:) That brings us to the third question that you must decide, and that is whether Mr. John R. Park is responsible for the conditions persisting. Let me talk generally about the kind of offense we have here. This is not an offense like a bank robbery. This is not an offense like a theft, a rape. This is not an offense where a member of the community, who, doesn't deserve any respect in the first place, probably by virtue of his lifestyle, goes out and commits a crime. This isn't the kind of conduct that one knows as criminal when he engages in it. You walk into a bank, stick a gun in a person's face, and the person who is acting knows he is committing a crime. He knows that it affronts a community standard. When you are talking about public health and public safety, different standards have to apply. The public cannot protect itself against certain forms of contamination. The law, therefore, (195)

imposes upon those persons who are going to deal in drugs or cosmetics or food, anything which may endanger human health, imposes upon those people who engage in that business a responsibility for knowing that they produce is healthful.

Now, Mr. John R. Park is the president and chief executive of Acme Markets. His responsibility, as he testified, includes all operations of the company. According to the bylaws of the company which were read to you by the vice-president and general counsel, Mr. Gilfillan, includes general and active supervision of all phases of the company's operations and business. Now, what should we interpret this to mean? Well, I wouldn't say that that means that Mr. Park should be standing outside of every warehouse waiting for a rat to try to get in. That would be simply impossible. What I think it should reasonably mean, though, is that, as president, he should be held responsible for setting up a system, a system of sanitation, of delegating responsibility in a way that he is sure the job will get done, of using Mr. Fahlhaber and Mr. Bronsdon, his various division vice-presidents, in a fashion that ensures that that responsibility, or anyone engaging in any business which may affect human health, does the job in a sanitary fashion.

Apparently, there was some such system, in a (196) sense. Mr. Fahlhaber was generally responsible, that is, another vice-president was generally responsible for the technical aspects of sanitation. Mr. Bronsdon, a very reputable sanitation engineer, was his subordinate in that business of the technical aspects of sanitation. But, it was Mr. McCahan, that is, a divisional vice-president, who, according to the testimony, was supposed to be responsible for everything that went on in the Baltimore division and, therefore, the Baltimore warehouse. Unfortunately, Mr. Bronsdon didn't work for him. Mr. Brondson worked up in Philadelphia. He worked under Mr. Fahlhaber. He would come down when there were requests and when there were problems, but he was up in Philadelphia. He wasn't under Mr. McCahan's direction down here.

That same kind of relationship had persisted not only in November of 1971, when these inspections occurred, and again in March of 1972, when these inspections occurred, they occurred back in March of 1970. In March of 1970, Mr. Park was informed that in a warehouse up in Philadelphia, the same kinds of problems that we have just presented evidence on, and which I just showed you photographs on, had existed up in a warehouse in Philadelphia. And, at that time, the same system for ensuring the sanitary conditions—that is, Mr. Fahlhaber and Mr. Bronsdon and a divisional vice-president. It was Mr. St. John or someone (197) in warehousing at the time. The same crew of people, with the exception of the fact that it arises in a different district or division, have allowed this to occur, potential rodent entryways were noted by ill fitting doors and doors in disrepair at southwest corner of warehouse. This is exactly what was uncovered in the November inspection of 1971 in Baltimore. It is the same condition that was uncovered in March of 1972 in the warehouse in Baltimore.

Number two, rodent nesting, rodent excreta pellets, rodent stained bale bagging and rodent gnawed holes noted among bales which were stored in the warehouse. Now, this was the Philadelphia warehouse. That is the same thing that happened in November of 1971 and March of 1972 in Baltimore.

The point is that, while Mr. Park apparently had a system, and I think he testified the system had been set up long before he got there—he did say that if anyone was going to change the system, it was his responsibility to do so. That very system, the system that he didn't change, did not work in March of 1970 in Philadelphia; it did not work in November of 1971 in Baltimore; it did not work in March of 1972 in Baltimore, and under those circumstances, I submit, that Mr. Park is the man responsible. The other people were part of the system. They may have had functions to perform. I dare say they probably failed (198) to perform their functions as they probably should have. The fact of the matter is that nobody was doing their job. When a system doesn't work, when a system breaks down three times, then the man at

the top, the man who sets the system, Mr. John R. Park, should be responsible.

* * * *

(212) Mr. Park was responsible for seeing that sanitation was taken care of, and he had a system set up that was supposed to do that. This system didn't work. It didn't work three times. At some point in time, Mr. Park has to be held responsible for the fact that his system isn't working, and I submit to you that that is why nothing was done at the Philadelphia warehouse the first time. Much ado was made about the fact that nothing was done the first time. Well, should we have done anything the first time? In the evidence before you, that is the first instance in which Mr. Park was put on notice that his system wasn't working. When things broke down in the Philadelphia warehouse, he should have been on notice that Mr. Fahlhaber and Mr. Bronsdon and his divisional vice-president weren't doing their jobs, whatever they were supposed to be doing, talking about the problems and talking about how to solve the problems, it wasn't getting done. At that point in time, Mr. Park should have known his system wasn't working, and he should have done something about it.

That was true, again, after the November inspection. It was again present in January of 1972. It (213) was saying, again, your system has broken down. It is not working. You have got to do something about it. What is done? What was done was all done through the same people, and when it was done in March of 1972, the warehouse was still contaminated.

The Government is not asking you to find Mr. Park guilty because the system broke down. It broke down three times. The first time nothing was done, and it shouldn't have been done. The man had to give Mr. Park a chance to create a system that would work. He didn't do it, and that is the reason you should hold him responsible.

* * * *

(220) [Jury instructions] (The Court:) Now, in this particular case, the Defendant is charged in five counts of violating the law.

The first four counts of the Information concern events that are alleged to have occurred in November and (221) December of 1971.

The first count involves certain boxes of gelatin dessert, Jello. Counts two, three and four involve flour and count five also involves flour, but the time period on count five is different, since this concerned events that occurred in January and February of 1972.

All the counts arise from the alleged rodent infestation of various forms.

The Defendant in this case is charged under Section 331(k) of Title 21 of the United States Code. That provision makes it a criminal offense to do any act with respect to food that is being held for sale after shipment in interstate commerce if the result is adulteration of that food.

In order to find the Defendant guilty on any count of the Information, you must find beyond a reasonable doubt on each count, first, that the food that was held was held for sale in the Acme warehouse after shipment in interstate commerce.

Secondly, that the food involved was held in unsanitary conditions in a warehouse with the result that it consisted, in part, of filth or where it may have been contaminated with filth.

Thirdly, that John R. Park held a position of authority in the operation of the business of Acme Markets, (222) Incorporated.

However, you need not concern yourselves with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets.

The corporation, Acme Markets, Incorporated, has already entered a plea of guilty to the charge placed against it, and, while that plea does not imply, in any way, the Defendant Park is guilty, the fact that the materials in question are foods held for resale after shipment in interstate commerce and held under unsanitary conditions are issues that are beyond question in the case and must be accepted by you.

The statute makes individuals, as well as corporations, liable for violations. An individual is liable if it is clear, beyond a reasonable doubt, that the elements of the adulteration of the food as to travel in interstate commerce are present. As I have instructed you in this case, they are, and that the individual had a responsible relation to the situation, even though he may not have participated personally.

The individual is or could be liable under the statute, even if he did not consciously do wrong. However, the fact that the Defendant is present and is a chief (223) executive officer of the Acme Markets does not require a finding of guilt. Though, he need not have personally participated in the situation, he must have had a responsible relationship to the issue. The issue is, in this case, whether the Defendant, John R. Park, by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose.

* * * *

(226) (Mr. Pierson) On behalf of the Defendant, we feel by the use of the word "responsible," when taken in connection with your use of the word "responsible" as a "responsible officer" may be confusing to the jury. There ought to be some definition of the word "responsible". There ought to be some definition that would be somewhat more broad than you have given in your charge, because you are using the word "responsible" in the legal sense, and the jury may very well be using the word in the colloquial sense.

(The Court) Anything else?

(Mr. Pierson) That is all, sir.

(Mr. Boyd) If I had been saying what Mr. Pierson just said, I would have reverted again to the suggestion I made to you in Chambers and that is, strange though it may seem, to have referred to Dotterweich. There is language in that case which you have not used in connection with your charge.

(The Court) There is language in there that I have not used, and I think it is mostly language that you would have not wanted me to use. I have read it, and I don't think you want me to use it.

(Mr. Boyd) I wanted to use it the way I understand it.

(The Court) I don't understand it the same way (227) you do.

(Mr. Boyd) I think the definition of "responsible" was far stricter and tighter than the law requires it to be.

(The Court) Let me say this, simply as to th definition of the "responsible relationship." Dotterweich and subsequent cases have indicated this really is a jury question. It says it is not even subject to being defined by the Court. As I have indicated to counsel, I am quite candid in stating that I do not agree with the decision; therefore, I am going to stick by it.

(Mr. Pierson) I don't think it is entirely clear in the decision whether he was "responsible." There is basically—

(The Court) You have your objection.

* * * *

Let the record show—I suppose you still have your objection and wish to renew your motion for judgment of acquittal?

(228) (Mr. Pierson) Yes.

As to the material on cross examination, we would like to move to strike what was admitted, subject to exception, that was just as to the Philadelphia matters.

(The Court) You objected at the time.

(Mr. Pierson) We would like to have the exception shown in the record.

(The Court) I understand.

Overruled. I have denied your motion for judgment of acquittal, and I do so again.

* * * *

Exhibit 23

DEPARTMENT OF HEALTH EDUCATION,
AND WELFARE

Public Health Service
Food and Drug Administration

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: 301-862-3396

January 27, 1972

Mr. John R. Park, President
Acme Markets, Inc.
124 North 15th Street
Philadelphia, Pennsylvania 19102

Dear Mr. Park:

We have recently completed a thorough review of the report of an inspection made of your Baltimore warehouse complex during the period of November 29, 1971 through December 14, 1971, as well as analytical reports of samples collected during this inspection.

We note with much concern that the old and new warehouse areas used for food storage were actively and extensively inhabited by live rodents. Of even more concern was the observation that such reprehensible conditions obviously existed for a prolonged period of time without any detection, or were completely ignored. This is evidenced by the many different lots of food products actually defiled by rodents. The details of such findings were set forth in a written list which was submitted to your warehouse management personnel at the conclusion of this inspection. In an effort to be helpful, we are attaching a copy of this list for your ready reference.

Although management at the warehouse during the course of this inspection was cooperative and on their own volition subsequently destroyed the food products in question; nevertheless, the gross insanitary conditions and actual food contamination as noted constitute a serious violation of the law.

We trust this letter will serve to direct your attention to the seriousness of the problem and formally advise you of the urgent need to initiate whatever measures are necessary to prevent recurrence and ensure compliance with the law.

Sincerely yours,

/s/ Norman Kramer
Food and Drug Officer
Baltimore District

Enclosure

cc: Mr. Robert McCahan
Vice President in Charge
of the Baltimore Division

Exhibit 24

ACME MARKETS, INC.
908 York Road, Towson, Md. 21204

Robert W. McCahan
Division Manager

February 7, 1972

Dr. Norman Kramer
Food and Drug Officer
U.S. Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201

Dear Dr. Kramer:

Mr. Park has asked me to write to you and give you a report on the steps we have taken to correct the situation relative to the findings set forth in the written list attached to your letter to Mr. Park dated January 27, 1972.

On Page One of the "List of Observations," Inspectors Brown and Merritt begin by summarizing the general conditions they found at our Distribution Center during the inspection period. They then go on to describe specific observations made in various parts of the complex. It will be my intention here to respond in the same sequence as listed on your report.

1. Increased efforts were made in baiting throughout the building for rodents. To the best of our knowledge, all rats have been eliminated and with the exception of a few isolated instances, all mice have been eliminated. During the inspection, the company's pest control contractor was called in with a crew of 4 men to properly bait the entire Distribution Center. Since that time, the pest control contractor has spent additional hours along with company personnel in the rodent elimination program.

2. The entire Distribution Center has been cleaned and, wherever possible, merchandise has been moved 18 inches away from the walls in order that these areas may be maintained in sanitary condition.

3. The entire building has been inspected and made as rodent-proof as possible.

4. All of the premises including those belonging to Acme and the adjacent railroad property have been cleaned of trash and treated for rodent infestation.

5. All of the rodent defiled food products encountered by the inspectors were destroyed in accordance with their requests and under their supervision.

The cost of this merchandise amounted to $15,425.46. In addition, we have destroyed miscellaneous small quantities of rodent defiled merchandise found by our own supervisory staff in the course of their daily duties.

6. All dry rodent bait boxes have been covered with heavy plywood to prevent containers from being damaged resulting in the spilling of rodenticides. Liquid bait stations have all been changed from plastic containers to either glass and metal or to a new type of small plastic container. These bait stations have been protected by a piece of steel so that they are available to the rodents and to the service men, but cannot be damaged by material handling equipment.

7. Hazardous household products found stored near food products have been relocated. At the time of the inspection, all non-food products were placed in pallet racks located below food products in order to avoid any possible contamination. At this point, we have all but completed the entire relocation of all non-food products to two specific aisles in the Distribution Center in order to completely separate this type of merchandise from food products.

8. As a result of observations relative to probable rodent entry to the buildings, we have made extensive repairs to overhead doors, unpainted surfaces, dock ladders, and all openings to prevent rodent entry.

The cost of this work was approximately $1,000.

9. All broken windows have been replaced.

10. Throughout the "List of Observations", the inspectors pointed out evidence of rodent infestation in the form of rat and mouse pellets, etc. All areas including selection areas, shipping and receiving platforms, storage boxes, and offices have been thoroughly cleaned and

scrubbed and are being maintained in clean condition.

In order to accomplish this work, we purchased a heavy duty scrubbing machine at a cost of $5,600. We hired 10 porters to supplement our existing sanitation crew at a continuing cost of approximately $1,000 per week.

We also have initiated the use of approximately 80 additional hours per week for material handling personnel for the express purpose of moving merchandise in order to permit adequate cleaning of the floor and wall surfaces. This effort represents an approximate additional cost of $500 per week.

11. We have installed rodent-proof ladders at the rail sidings to enable receiving personnel to get to the track level. All wooden pallets formerly used for this purpose have been removed.

12. Caustic cleaning materials, etc. have been removed from the selection and storage areas of the Distribution Center and are now kept in the maintenance areas.

13. We have initiated more stringent control on rotation.

14. All melon and pumpkin crates containing straw have been thoroughly cleaned and removed to a section of our north trailer lot.

15. We have reduced the over-crowded condition in the warehouse by reducing inventory. It is our intent to maintain the inventory at a level that will permit cleaning as well as afford mobility to the material handling equipment throughout the Distribution Center.

16. In many aisles that were at the time of the inspection dimly lit, fluorescent lighting fixtures have been installed.

17. All fluorescent lights in the bakery processing area have been covered with plastic shields and the remainder of all lights throughout the bakery shall be covered in the near future.

Perhaps of greatest importance has been the effort made by William Bronsdon, Sanitation and Inspection Engineer, and his associates and Edwin Zahn, Distribution Center Manager, and his supervisory staff. Meetings were held with each shift of the warehouse operation on

company time for the purpose of reviewing and informing all personnel of the required standards with regard to sanitation which must be maintained. I think Messrs. Bronsdon and Zahn covered the area very thoroughly and were particularly pleased with the positive response from our employees.

As part of our continuing program, weekly inspections of the Distribution Center facility have been made by both Corporate and Division sanitation personnel in order to insure maintenance of sanitary conditions.

I believe that you will agree that we have made strenuous and expeditious efforts to correct the unfortunate situation disclosed in said list. I want to assure you that we will do our utmost to fully comply with all of the statutes, rules, regulations, and orders applicable to matters of this nature and to prevent any recurrence of this situation in the future.

Sincerely,

/s/ Robert W. McCahan

cc: Mr. John R. Park
RWMcC/dew

GOVERNMENT EXHIBIT 27

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 24, 1970

Acme Markets Inc.
124 N. 15th St.
Phila., Penna.
Attn: Mr. John Parks, President

Dear Mr. Parks:

This letter is written in response to widespread industry requests for reports to top management of inspectional findings of significant adverse conditions which should be corrected.

An inspection was made of your firm at 59th and Upland Way, Phila., Pa. on March 23, 26, 1970 by inspectors from our Philadelphia Office. The inspectors left written lists of observations and discussed the observations with the management at this location.

The inspection revealed objectionable conditions in your food storage warehouse. Objectionable conditions included:

1. Potential rodent entry ways were noted via ill fitting doors and door in irrepair at Southwest corner of warehouse; at dock at old salvage room and at receiving and shipping doors which were observed to be open most of the time.
2. Rodent nesting, rodent excreta pellets, rodent stained bale bagging and rodent gnawed holes were noted among bales of flour stored in warehouse.
3. Potential rodent harborage was noted in discarded paper, rope, sawdust and other debris piled in corner of shipping and receiving dock near bakery and warehouse doors. Rodent excreta pellets were observed among bags of sawdust (or wood shavings).

This letter is not intended to imply that the Food and Drug Admin. will or will not recommend any civil or

criminal action. The letter in no way relieves your firm or its personnel from all responsibility to take steps to assure compliance with the Food, Drug and Cosmetic Act. It is not intended as an all inclusive report on objectionable conditions. It must not be used in part or in whole in the promotion of your firm's products or facility.

Sincerely yours,

IRWIN B. BERCH
District Director

SRY/sg
cc: Penna. Dept. of Health

JUDGMENT OF CONVICTION

(34) (The Court) Gentlemen, as to Count I, it is adjudged that the Defendant pay a fine to the United States in the sum of $50.00.

As to Count II, it is adjudged that the Defendant pay a fine to the United States of $50.00.

As to Count III, it is adjudged that the Defendant pay a fine to the United States in the sum of $50.00.

As to Count IV, it is adjudged that the Defendant pay a fine to the United States in the sum of $50.00.

(35) As to Count V, it is adjudged that the Defendant pay a fine to the United States in the sum of $50.00.

GOVERNMENT'S REQUESTED INSTRUCTION NO. 3

In order to find a defendant guilty on any count, you must find beyond a reasonable doubt for that count:

1. That the food involved was held for sale in the defendant's warehouse after shipment in interstate commerce.
2. That the food involved was held under insanitary conditions in the warehouse with the result that it consisted in part of filth *or* whereby it *may* have become contaminated with filth.
3. As to the corporate defendant, Acme Markets, Inc., that the food was held for sale in the Acme Markets, Inc., warehouse, in the conduct of its business.
4. As to the defendant, John R. Park, that he held a position of authority and responsibility in the operation of the business of Acme Markets, Inc.

21 U.S.C. 331(k)

21 U.S.C. 342(a)(3)

21 U.S.C. 342(a)(4)

United States v. *Dotterweich*, 320 U.S. 277 (1943)

Berger v. *United States*, 200 F.2d 818 (C.A. 8, 1952)

United States v. *Kaadt*, 171 F.2d 600 (C.A. 7, 1948)

SUPREME COURT OF THE UNITED STATES

No. 74-215

UNITED STATES, PETITIONER

v.

JOHN R. PARK

ORDER ALLOWING CERTIORARI—Filed November 11, 1974

The petition herein for a writ of certiorari to the United States Court of Appeals for the Fourth Circuit is granted.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1974 564960 82

Supreme Court, U. S.
FILED
OCT 4 1974
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-215

UNITED STATES OF AMERICA, Petitioner

v.

JOHN R. PARK

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

BRIEF FOR RESPONDENT IN OPPOSITION

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IN THE

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No. 74-215

UNITED STATES OF AMERICA, Petitioner

v.

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ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

BRIEF FOR RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinions in the court of appeals are printed as Appendix A, pp. 1A-12A, to the petition and reported in 499 F.2d at 839.

JURISDICTION

The judgment of the court of appeals was entered on July 2, 1974. On July 26, 1974, Mr. Chief Justice Burger extended to August 31, 1974, the time within which to file a petition for a writ of certiorari. The petition was filed on August 30, 1974.

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

QUESTIONS PRESENTED

1. In the trial of an individual charged with the crime of doing or causing acts resulting in the adulteration of food:

(a) should the trial court have instructed the jury that the prosecution was not required to show any wrongful intent or awareness of wrongdoing by the accused, but was required to show some act or acts of commission or ommission by the accused which caused the adulteration of the food; and

(b) did the trial court confuse the jury by instructing them, in language quoted from the dissenting opinion of Mr. Justice Murphy in *United States* v. *Dotterweich,* 320 U.S. 277, 285-86, that the accused might be convicted if the jury found that he held a position of "authority and responsibility" in the business of the corporation of which he was president, without regard to his personal responsibility, if any, for the acts which caused the adulteration of the food?

2. In the prosecution conducted below on the erroneous theory that the accused might be convicted merely by showing that he held a position of authority and responsibility in a corporation, did the prosecution's introduction of evidence of an alleged prior offense, remote as to both time and place, require reversal since, on the prosecutor's own theory, there was no need which would outweigh the prejudice resulting from such evidence (although in a retrial conducted in accordance with the majority opinion in *Dotterweich,* 320 U.S. 277, such evidence might be admissible)?

STATUTE INVOLVED

Section 301(k) of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1042, as amended, 21 U.S.C. § 331(k), provides:

The following acts and the causing thereof are prohibited:

* * * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

STATEMENT

Respondent John R. Park was tried in the United States District Court for the District of Maryland for alleged violations of Section 301(k) of the Food, Drug and Cosmetic Act, *supra,* based on the presence of rodents in a portion of the Baltimore warehouse of Acme Markets, Inc.

1. Acme is a national retail food chain employing approximately 36,000 persons in 874 retail outlets. The company has twelve main warehouses and four special

warehouses. Park is President and chief executive officer with his office in Acme's corporate headquarters in Philadelphia (App. 5A n.5; Joint Appendix 41).

Acme's "Division 6" is headed by a Divisional Vice President with his office in Towson, Maryland, and consists of a warehouse complex in Baltimore and approximately 110 retail outlets. The Baltimore warehouse was described as a large complex of approximately 250,000 square feet including an "older building" of three stories with a basement. An inspection of this facility, which took 12 days in November and December 1971, discovered rodent infestation in a portion of the basement of the older building (J.A. 18-20). The government's own evidence established that "a great deal of effort was made in the way of cleaning up the warehouse" (J.A. 23) following the 1971 inspection, and also that there was some evidence of infestation by mice during a subsequent inspection in March 1972. At least one structural deficiency which might have contributed to the March 1972 infestation—a rusted door—was not noticed by the Food and Drug Administration until the second inspection (J.A. 26).

An informal hearing was held in June 1972 at the local office of the FDA in Baltimore and was attended by the Divisional Vice President and other officers of Acme, not including Park. No further action was taken by the FDA until March 1973 when a five-count information was filed in the District Court charging Acme and Park with violations of 21 U.S.C. § 331(k), quoted *supra* at p. 3, which prohibits adulteration of foods shipped in interstate commerce while held for sale. Four counts related to violations discovered in the November and December 1972 inspection; the fifth count involved a single violation found in the March 1972 inspection.

Prior to trial, Park filed a Motion for Bill of Particulars (J.A. 10) seeking the particulars of Park's alleged liability for the violations. The government responded to the motion by disclosing that the evidence would not show that defendant Park personally performed any of the acts described in the information but that "the Government's evidence will simply show that the defendant was a corporate officer who, under law, bore a relationship to the receipt and storage of food which would subject him to criminal liability under *United States* v. *Dotterweich*, 320 U.S. 277 (1943)" (J.A. 14-15). The trial court accordingly declared moot the Motion for Bill of Particulars.

The government demanded trial to a jury. Prior to the commencement of the trial, defendant Acme Markets, Inc. pleaded guilty to each count. Notwithstanding Acme's plea, and over objection by respondent Park, the prosecutor submitted detailed evidence concerning each of the alleged violations. No evidence was presented that any contaminated food had actually been offered for sale.

The government's evidence against Park consisted largely of a reading of the By-Law of Acme Markets, Inc. which stated that the chief executive officer of the company had "general and active supervision of the affairs, business, offices and employees of the company" (J.A. 40).

The trial court accepted the arguments made by the prosecutor that Park's criminal liability could only be determined by the jury and therefore declined judgment of acquittal (J.A. 42, 59, 66). Park testified in his own defense concerning the care taken in sanitation matters; on cross-examination he acknowledged that he was chief executive officer of Acme and therefore ultimately responsible for anything which occurred in the company (J.A. 57).

Over objection, the prosecutor introduced detailed evidence concerning an alleged prior offense involving a rodent infestation in Acme's Philadelphia warehouse in March 1970 (J.A. 51-55). The evidence of this alleged prior offense was repeatedly referred to by the prosecutor and emphasized in his summation (J.A. 60-62).

The trial court's charge to the jury was largely taken from the government's requested instructions. On the crucial instruction concerning Park's personal liability, to which defendant took vigorous exception, the court stated that the jury might convict Park if they found that respondent "held a position of authority and responsibility in the business of Acme Markets" (J.A. 63). The text of the charge quoted in the petition (pp. 5-6) omits those portions which the court of appeals found most objectionable and confusing. For the convenience of the Court, the entire substantive text of the charge as designated for inclusion in the Joint Appendix (and which omitted only the standard language concerning crediability of witnesses, burden of proof, and other matters not in dispute in the instant case) is reprinted as Appendix C to this brief (*infra*, pp. 17-18). The jury returned a verdict of guilty on all counts.

Extensive post-trial proceedings were had in which defendant renewed his objections to the charge and the admission of evidence, and also sought an acquittal on motions and affidavits alleging an abuse of prosecutorial discretion in the government's having prosecuted Park solely because of his position as chief executive officer and notwithstanding his lack of any direct connection with the Baltimore violations, contrary to the government's long-standing practice in all other reported and unreported cases (J.A. 72-144). The trial court initially indicated a belief that the defense of abuse of prosecutorial discretion had been made out and that the motion for acquittal should be granted (J.A. 133). The court subsequently concluded that "this case comes as close to an abuse of that discretion as any one you would find," but that the court should not "impose its own feelings" and therefore "reluctantly" concluded that the motion must be denied (App. 143-144). The court then imposed a fine of $50 on each of five counts, substantially less than the one

year's imprisonment or $1,000 fine, or both, provided for a first offense under 21 U.S.C. § 333(a), stating that by imposing this sentence he would "reinforce" his previous "comments" on the merits of the prosecution's case (J.A. 144).

2. A divided panel of the court of appeals reversed the judgment of conviction and remanded the case for a new trial. The majority held that the charge did not correctly state the law as declared in *United States* v. *Dotterweich*, *320* U.S. 277. The court stated that *Dotterweich* dispensed with the need to prove "awareness of wrongdoing" by Park but did not dispense with the need to prove that Park was "in some way personally responsible for the act constituting the crime" (App. 4A). The court concluded that since the statute prohibits "causing" the adulteration of food, the conduct required to be proved would be "acts of the accused which *cause* the adulteration of such food"(App. 4A). (Emphasis by the court of appeals.) The court enlarged upon this standard by stating that such "action" by respondent "may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' the contamination of the food" (App. 6A).

In response to the contention that the requirement of such proof would make enforcement more difficult, the court stated:

> "Nevertheless, the requirements of due process are intended to favor fairness and justice over ease of enforcement. We perceive nothing harsh about requiring proof of personal wrongdoing before sanctioning the imposition of criminal penalties." (App. 6A.)

The court also held that the evidence of an alleged prior offense, not charged in the information, should

have been excluded because, as the case was tried and submitted to the jury, "there was no actual need for the Philadelphia evidence" (App. 8A). The court expressly allowed the district court on retrial "to determine the admissability of this 'prior crime' evidence in light of developments" (App. 9A).

REASONS FOR REFUSING THE WRIT

A. The decision below is correct.

Reversible error was committed in the trial court's instructions to the jury because the prosecutor induced the trial court to rely *not* on the "opinion of the Court" in *Dotterweich,* delivered by Mr. Justice Frankfuter for a five-Justice majority, 320 U.S. at 278-85, but instead to rely on the language and reasoning of the *dissenting* opinion written by Mr. Justice Murphy. 320 U.S. at 285-93.

The Solicitor General has continued this error by again relying, at page 9 of the instant petition, on Mr. Justice Murphy's dissent as the authoritative opinion in the *Dotterweich* case. The petition argues (p. 9) that the jury in *Dotterweich* convicted a corporate officer:

> "even though he had no personal knowledge of the misconduct involved, and there was no evidence of any 'personal guilt' on his part. 320 U.S. at 286 (Murphy, *J.* dissenting)."

The opening paragraph of the dissent in *Dotterweich* states the argument of the four-Justice minority against affirmance of the conviction of a corporate officer. According to Mr. Justice Murphy:

> "There is no evidence in this case of any personal guilt on the part of the respondent. . . . Guilt is imputed to the respondent solely on the basis of his authority and responsibility as president and general manager of the corporation." 320 U.S. 285-86.

One of the government's requested instructions submitted to the trial court in the instant case also sought to impute guilt to respondent Park "solely on the basis of his authority and responsibility as president" of Acme. This instruction (No. 3) was intended by the government to summarize four factual elements necessary to convict both Acme and Park. The first two elements referred to factual proof of interstate shipments and the holding of goods under unsanitary conditions; the third element referred to Acme's liability (and became irrelevant when Acme pleaded guilty); the text of the fourth element, in its entirety, was as follows:

> "4. As to the defendant, John R. Park, that he held a position of authority and responsibility in the operation of the business of Acme Markets, Inc."

This text is followed by citations to *Dotterweich* and two other cases, *United States* v. *Berger,* 200 F.2d 818 (8th Cir. 1952), and *United States* v. *Kaadt,* 171 F.2d 600 (7th Cir. 1949).

Neither the court of appeals decisions nor the opinion of the Court in the *Dotterweich* case contains the language requested by the prosecutor; that language appears only in the dissent by Mr. Justice Murphy.

The trial court charged the jury on the crucial issue of Park's liability in the exact words requested by the prosecutor. After defining the elements of interstate shipment and unsanitary conditions, the trial court stated:

> "Thirdly, that John R. Park held a position of authority in the operation of the business of Acme Markets, Incorporated.

> "However, you need not concern yourselves with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets." (J.A. 63).

This portion of the charge, combined with other portions reflecting the view that criminal liability might exist without evidence of any "personal guilt" on the part of the respondent, as Mr. Justice Murphy contended had been done in *Dotterweich* and as the Solicitor General now contends in the instant petition (p. 9), caused the court of appeals to reverse.

The court of appeals was correct in rejecting the contention that a conviction could be had without evidence of any "personal guilt," because the *Dotterweich* opinion does require proof of personal guilt, although not proof of awareness of wrongdoing by the defendant.

The *Dotterweich* prosecution was against both a corporation in business as a drug jobber and a corporate officer. Contrary to Mr. Justice Murphy's claim that there was "no evidence of personal guilt on the part of the respondent [Dotterweich]," the printed Record filed in this Court shows not only that Dotterweich was personally responsible for every aspect of the corporate defendant's business but also that he testified at trial in a manner which emphasized that personal responsibility.

The violations charged in the case arose from two shipments of digitalis alleged to be less potent than required by law and a shipment of pills alleged to be misbranded because the contents, although correctly stated on the label, did not conform with the National Formulary definition. The defendants vigorously defended on the merits of every issue, claiming that the digitalis was of proper potency, attacking the government's tests, and contending that the pills were properly labeled. Except

for expert witnesses, the defendant's testimony was presented by Dotterweich himself, who was called and recalled on four separate occasions in a two-day trial (Record 125, 140, 156, 159). The evidence showed that the corporate defendant had been "created" (in the words of defense counsel) (R. 63) by Dotterweich, was owned by him, had approximately 26 employees, working on one floor of an office building, with Dotterweich as president, "General Manager," and the only supervisor. During testimony by Dotterweich, his counsel almost invariably used the word "you" to refer to actions taken in respect of the challenged shipments even when referring to actions taken by other employees who worked under Dotterweich's supervision, such as "I show you the original order that *you* sent" (R. 128); "did you *buy* any digitalis tablets from any other concern?" (R. 141); and "Mr. Dotterweich, did *you* continue so to sell digitalis tablets from that batch after that?" (R. 142). (Emphasis added.) On cross-examination, Dotterweich admitted that "When I am in the place, I am in charge," that he was "the boss," and that he must have been in charge on a day when one of the challenged shipments went out since he had signed a letter that day in his capacity as "General Manager" (R. 143-44).

The jury in the *Dotterweich* case found the individual defendant Dotterweich guilty on all counts but disagreed as to the guilt of the corporation. The verdict is readily explained by the extent to which the defendant's evidence had been identified with Dotterweich personally, particularly by the use of the words "I," "my," "his," and "you," while the corporate defendant was infrequently referred to except in the formal identification of documents and other exhibits.

The court of appeals carefully considered the evidence shown in the Record in the *Dotterweich* case, and compared that evidence with both the charge and the evidence adduced against respondent Park in the instant case, before concluding that "the facts of *Dotterweich* estab-

lished the personal responsibility which we find lacking in the case before us" (App. 3A-4A n.3).

The charge not only quoted from, and relied on, the dissenting opinion in *Dotterweich,* but also misconstrued an important phrase from the opinion of the Court. Near the end of the charge, the trial court instructed the jury that Park might be convicted if he "had a responsible relation to the situation, even though he may not have participated personally" (J.A. 64). This statement was inconsistent with the holdings in *Dotterweich.* The words "responsible relation" are used at two places in the opinion, 320 U.S. at 281, 285, but not as a substitute for a defendant's having "participated personally" in the offense. To the contrary, the first use of "responsible relation" is in reference to persons "acting at hazard," 320 U.S. at 281, and the second use is in connection with the "variety of conduct" which may constitute an offense. 320 U.S. at 285. The opinion uses a similar phrase, "such a responsible share," 320 U.S. at 284, to define those who may have committed an offense. All three uses of the word "responsible" are closely tied to the holding, also at page 284, to the effect that the individuals who may be convicted of violations of the Act are those "who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor."

The government also seeks to rely on a comparison of the charge in the trial court in the instant case with the actual text of the charge given by the district court in *Dotterweich* (Petition, 13 n.6). But the actual charge given in *Dotterweich* is not a satisfactory model for the instant case because in *Dotterweich* both defendants sought to establish the defense that no violation whatsoever had been committed, rather than the defense asserted in the instant case that a particular individual was not criminally liable for conceded violations by a corporate defendant; instructions appropriate to the latter defense were neither requested nor desired in the *Dotterweich* case.

B. Enforcement of the Act will not be impeded by the requirement that the prosecution establish acts of commission or omission which caused the violations.

The requirement that individual criminal liability be established by proof of acts of commisson or omission by the accused "which cause the adulteration" of the food (App. 4A) is derived directly from the text of the Act itself, *supra* at p. 3, by which "the following *acts* and the *causing thereof* are prohibited . . ." (Emphasis added.) Unless this requirement were to be deleted by amendment to the Act, there would be no proper occasion for a construction of the statute which would allow guilt upon lesser evidence, regardless of any effect upon the government's ease of obtaining convictions.

But the record of enforcement of the Act, as reflected in reported appellate decisions, shows that the government has rarely, if ever, attempted to establish individual criminal liability in cases which did not involve facts to establish "the personal responsibility" which the court of appeals found "lacking" in the instant case (App. 4A). The reported decisions relied on in the petition (pp. 11-12) all involved such facts. In *H.B. Gregory Co.* v. *United States,* No. 73-1744 (7th Cir.), decided March 14, 1974, pending on petition for a writ of certiorari, No. 74-142, the facts established that the individual defendant "was in charge of the sanitation program and specifically the rodent control program in the warehouse; and that he was there on a daily basis" (Appendix 1 to the petition, opinion of the court of appeals, pp. 5-6). In *United States* v. *Shapiro,* 491 F.2d 335 (6th Cir. 1974), the individual defendant had *pleaded guilty* and received a "probated two-year sentence" conditioned upon compliance in the future with the Act. The holding of the court of appeals that the defendant could not avoid revocation of his probation by pleading the defense that the business was

subject to agreement of sale at the time of the violations is entirely consistent with the holding of the court of appeals in the instant case. *United States* v. *Cassaro, Inc.,* 443 F.2d 153 (1st Cir. 1971), involved evidence (appearing from the opinion to have been uncontested) that the individual defendant ordinarily was present at the bakery in which the violations were found and was personally in charge of its operations. 443 F.2d at 154, 157. The individual defendant's only contention on appeal was that he had been temporarily "out sick" at the time of the inspection. In *Lelles* v. *United States,* 241 F.2d 21 (9th Cir. 1957), *cert. denied,* 353 U.S. 974, the individual defendant was charged with having "personally" caused the offenses, 241 F.2d at 24, and was convicted even though the corporate defendant was ordered acquitted. *United States* v. *Kaadt,* 171 F.2d 600 (7th Cir. 1948), is a case similar to *Dotterweich* in which the individual defendants took responsibility for distributing a drug, with printed matter signed by one of the individual defendants, but contended that no violation whatsoever had been committed by anyone, corporation or individual. *United States* v. *Parfait Powder Puff Co.,* 163 F.2d 1008 (7th Cir. 1947), *cert. denied,* 332 U.S. 851, does not involve individual criminal liability. In *United States* v. *Diamond State Poultry Co.,* 125 F. Supp. 617 (D. Del. 1954), the two individual defendants were so much a part of the activities from which the violations arose that the court expressly found for the purpose of sentence that there was "an identity between individual and corporate defendants . . . ." 125 F. Supp. at 620.

In none of these cases did the government attempt to establish individual criminal liability without proof of acts of the accused which caused the violations.

Rather than representing a typical example of government enforcement of the Act, the instant prosecution is an unprecedented effort to extend individual criminal liability beyond the limits established by the text of the Act itself, by the opinion of this Court in *Dotterweich,* and by the government's own previous good sense and sound discretion in prosecuting individuals only when evidence of personal responsibility has been established.

C. No occasion exists to review the conclusion of the court of appeals that "prior crimes" evidence had been introduced at trial without any purpose which might have outweighed the prejudice created to respondent.

The uniform rule is that evidence of other criminal offenses by a defendant, not charged in the indictment or information, is not admissable for any purpose, subject to very narrow and specific exceptions. *Boyd* v. *United States,* 142 U.S. 450, 458. In the instant case the government did not establish any purpose for the admission of such evidence which would have outweighed the prejudice resulting to respondent. The court of appeals concluded that "whether the need for and the persuasiveness and relevance of such evidence may outweigh its prejudicial effect, will, in large part, depend upon the prosecution's new approach to the presentation of its case" and left to the district court the determination whether or not to admit the "prior crime" evidence "in light of developments" in the new trial (App. 9A).

This portion of the court of appeals decision imposes on the government nothing more onerous than the obligation to justify with some sound reason the introduction of highly prejudicial evidence. A determination by this Court of the appropriate rule, if different from that declared in *Boyd,* 142 U.S. at 458, should await developments in the new trial, rather than occur against the background of a confused charge predicated upon an erroneous theory of individual criminal liability.

CONCLUSION

For the reasons stated, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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Attorney for Respondent

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APPENDIX C

INSTRUCTIONS TO THE JURY
(as designated for inclusion in Joint Appendix 62-64.)

* * * * *

Now, in this particular case, the Defendant is charged in five counts of violating the law.

The first four counts of the Information concern events that are alleged to have occurred in November and December of 1971.

The first count involves certain boxes of gelatin dessert, Jello. Counts two, three and four involve flour and count five also involves flour, but the time period on count five is different, since this concerned events that occurred in January and February of 1972.

All the counts arise from the alleged rodent infestation of various forms.

The Defendant in this case is charged under Section 331(k) of Title 21 of the United States Code. That provision makes it a criminal offense to do any act with respect to food that is being held for sale after shipment in interstate commerce if the result is adulteration of that food.

In order to find the Defendant guilty on any count of the Information, you must find beyond a reasonable doubt on each count, first, that the food that was held was held for sale in the Acme warehouse after shipment in interstate commerce.

Secondly, that the food involved was held in unsanitary conditions in a warehouse with the result that it consisted, in part, of filth or where it may have been contaminated with filth.

Thirdly, that John R. Park held a position of authority in the operation of the business of Acme Markets, Incorporated.

However, you need not concern yourselves with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets.

The corporation, Acme Markets, Incorporated, has already entered a plea of guilty to the charge placed against it, and, while that plea does not imply, in any way, the Defendant Park is guilty, the fact that the materials in question are foods held for resale after shipment in interstate commerce and held under unsanitary conditions are issues that are beyond question in the case and must be accepted by you.

The statute makes individuals, as well as corporations, liable for violations. An individual is liable if it is clear, beyond a reasonable doubt, that the elements of the adulteration of the food as to travel in interstate commerce are present. As I have instructed you in this case, they are, and that the individual had a responsible relation to the situtation, even though he may not have participated personally.

The individual is or could be liable under the statute, even if he did not consciously do wrong. However, the fact that the Defendant is present and is a chief executive officer of the Acme Markets does not require a finding of guilt. Though, he need not have personally participated in the situation, he must have had responsible relationship to the issue. The issue is, in this case, whether the Defendant, John R. Park, by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose.

• • • • •

No. 74-215

In the Supreme Court of the United States

OCTOBER TERM, 1974

UNITED STATES OF AMERICA, PETITIONER

v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE UNITED STATES

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In the Supreme Court of the United States

OCTOBER TERM, 1974

No. 74–215

UNITED STATES OF AMERICA, PETITIONER

v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE UNITED STATES

OPINION BELOW

The opinion of the court of appeals (Pet. App. 1A–12A) is reported at 499 F. 2d 839.

JURISDICTION

The judgment of the court of appeals was entered on July 2, 1974 (Pet. App. 13A). On July 26, 1974, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including August 30, 1974. The petition was filed on August 30, 1974, and granted on November 11, 1974 (A. 73). The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether, in a prosecution of a corporate officer for doing or causing acts resulting in the adulteration of food, an instruction that the jury may convict if it finds that the defendant had a responsible relation to the situation, but which does not also require a finding of particular acts of omission or commission or gross negligence by the officer, accords with the standards of *United States* v. *Dotterweich*, 320 U.S. 277.

2. Whether evidence that the president of a supermarket chain was on notice of insanitary conditions in his firm's Philadelphia warehouse in March 1970, was admissible to rebut his defense of justifiable reliance on subordinates, or to show his failure adequately to supervise them, with respect to insanitary conditions in the chain's Baltimore warehouse in 1971 and 1972.

STATUTES INVOLVED

Section 301(k) of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1042, as amended, 21 U.S.C. 331(k), provides:

The following acts and the causing thereof are prohibited:

* * * * *

> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce

> and results in such article being adulterated or misbranded.

Sections 303(a) and (b) of the Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1043, as amended, 21 U.S.C. 333(a) and (b) provide:

> (a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
>
> (b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $1,000, or both.

Section 402(a) of the Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1046, as amended, 21 U.S.C. 342(a), provides in part:

> A food shall be deemed to be adulterated * * * (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health * * *

STATEMENT

A. THE PROCEEDINGS IN THE DISTRICT COURT

In a five-count information filed in the United States District Court for the District of Maryland, the United States charged Acme Markets, Inc., a large

food store chain,[1] and its president, John R. Park, with violating Section 301(k) of the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 331(k). The information alleged that the defendants had caused five lots of food which were being held for sale after shipment in interstate commerce to become adulterated "in that * * * [they] consisted in part of a filthy substance by reason of the presence in said food of rodent pellets, rodent hairs and by reason of being rodent gnawed * * * [and] in that said food was held under insanitary conditions whereby it may have become contaminated with filth" (A. 5). See 21 U.S.C. 342(a)(3) and (4) *supra,* p. 3.

Acme pleaded guilty to each count of the information. On May 10, 1973, after a jury trial, Park was found guilty on all five counts of the information and was subsequently sentenced to pay a total fine of $250.

At trial, the parties stipulated that the food lots involved had been shipped in interstate commerce and were being held for sale in the Baltimore warehouse (Tr. 34–38). A Food and Drug Administration (FDA) investigator testified that in the November–December 1971 inspection of the basement of the Baltimore warehouse (A. 20–21):

> We found extensive evidence of rodent infestation in the form of rat and mouse pellets throughout the entire perimeter area and along the wall.

[1] Acme is a nationwide chain with approximately 36,000 employees, 874 retail outlets, twelve main warehouses, and four special warehouses, located in various parts of the country. The company headquarters, including respondent's office, is located in Philadelphia, Pennsylvania (Pet. App. 5A).

> We also found that the doors leading to the basement area from the rail siding had openings at the bottom * * * large enough to admit rodent entry. There were also rodent pellets found on a number of different packages of boxes of various items stored in the basement, and * * * there were also broken windows along the rail siding.

On the first floor, the inspectors found (A. 22):

> Thirty mouse pellets on the floor along the walls and on the ledge in the hanging meat room. There were at least twenty mouse pellets beside bales of lime Jello and one of the bales had a chewed rodent hole in the product. We also saw two hundred mouse pellets in the perimeter area of the Jello storage area. There were several hundred rat and mouse pellets along walls and in corners and on pallets of wild bird food.

The evidence also established numerous other insanitary conditions such as rat and mouse urine and nesting material in and around food, live and dead rodents in the warehouse, liquid drain cleaners stored near cooked ham, extremely overcrowded conditions, and accumulated trash (A. 21–22; Gov't Exh. 4).

Following the inspection, Dr. Norman Kramer, Chief of Compliance of the FDA's Baltimore office, wrote to Park on January 27, 1972, advising him of the conditions at the Baltimore warehouse (A. 64). The letter specifically informed Park that the Baltimore warehouse was "actively and extensively inhabited by live rodents" and that these conditions had "obviously existed for a prolonged period of time without any detection, or were completely ignored." Dr. Kramer testified that he sent a copy of the letter

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to Robert W. McCahan, Acme's Baltimore Division Vice President, as "[o]ne of the head men of * * * [the Baltimore] operation" (A. 33). The others with responsibility he named were officials in the corporate headquarters in Philadelphia: Mr. Park, Acme's president; Mr. Fahlhaber, the vice president for engineering; Mr. Hammel, the executive vice-president for sales and operations; and Mr. Bronsdon, Acme's sanitary inspection engineer (A. 33, see A. 36; A. 49).[2]

In March 1972, FDA conducted a second inspection of the Baltimore warehouse. While the inspector noted some improvement in the sanitary condition of the warehouse, he also found further evidence of rodent infestation. The Baltimore warehouse still contained rodent nesting material, dead rodents, damaged liquid bait traps, poorly fitted exterior doors, and rodent-contaminated food products (A. 23).[3]

Acme's general counsel, Mr. Gilfillan, identified Park at trial as the president and chief executive officer of Acme and read the company bylaws describing Park's duties. The bylaws provide that the chief executive officer "shall, subject to the board

[2] On February 7, 1972, McCahan, upon the direction of Park, responded to the letter. McCahan's letter claimed that the warehouse and adjacent property were cleaned, increased efforts were made in baiting for rodents, the building was inspected and potential rodent entry points repaired, hazardous household products were relocated away from food products, and additional cleaning equipment was purchased and additional personnel hired to keep the warehouse clean (A. 66).

[3] The first four counts of the information (A. 4–9) described violations observed during the November and December 1971 inspection, while the fifth count described violations observed during the March 1972 inspection (*ibid.*).

of directors, have general and active supervision of the affairs, business, offices, and employees of the company." He testified that Park functions by delegating duties, but that Park was responsible for seeing that his appointees "all work together." He added that sanitation responsibilities were delegated to Mr. Fahlhaber and Mr. Bronsdon (A. 40–41).

At the close of the government's case-in-chief, respondent moved for a judgment of acquittal on the ground that "Mr. Park is not personally concerned in this Food and Drug violation." The trial court denied the motion, stating that *United States* v. *Dotterweich*, 320 U.S. 277, "still seems to be the last word in this area. Whatever I might think of it, it has not been changed by Congressional action. I assume that the Congress had not acted, knowing the results of that case. It seems to me that case would be controlling here and says, in effect, the ultimate judgment should rest with the jury" (A. 42).

Park was the only defense witness. He testified that, while all company employees were under his direction, he employed a system of delegated responsibilities under which he had assigned the responsibility for sanitation to various other persons within the corporation (A. 43–46). He admitted having read the January 27 letter sent to him by FDA advising him of the insanitary condition of the Baltimore warehouse and described the action he undertook in response to the letter as follows (A. 47):

> A. [Mr. Gilfillan, Acme's general counsel] told me that he had discussed the matter with Mr. McCahan and that Mr. McCahan was in-

vestigating the situation immediately and would be taking corrective action and would be preparing a summary of the corrective action to reply to the letter.

* * * * *

Q. Well, aside from what you did, or aside from what Mr. Gilfillan did for you, what could you have done? Is there anything you could have done?

A. I don't believe there was anything I could have done more constructively than what I found was being done.

Q. And you were satisfied with what was being done?

A. Yes, sir.

On cross-examination Park conceded that sanitation "is a thing that I am responsible for in the entire operation of the company" and stated that he assigned this phase of the company's operation to "dependable subordinates" (A. 48–49).

Park was then cross-examined with respect to, and admitted having read, a letter addressed to him from FDA regarding insanitary conditions in Acme's Philadelphia warehouse in March of 1970.[4] In that letter (Gov't Exh. 27, A. 70–71), dated April 24, 1970, Park was advised that discarded paper and other debris providing potential rodent harborage, ill-fitting doors providing potential rodent entryways, and "[r]odent nesting, rodent excreta pellets, rodent stained bale bagging and rodent gnawed holes" had been observed at Acme's Philadelphia warehouse. Park acknowledged

[4] Counsel for Park objected to all questions concerning the Philadelphia incident (A. 51).

that, with the exception of the divisional vice-president, the same corporate officials have responsibility for sanitation in both Baltimore and Philadelphia (A. 54–55).

Park then described his responsibilities with respect to the insanitary conditions as follows (A. 55):

Q. And after the same problem occurred twice, once in Philadelphia and once in Baltimore, did you have any reason to believe that the system you had set up of handling sanitation, the responsibilities you had delegated to others for sanitation, that system just wasn't working, sir?

A. Well, the fact that this occurrence occurred in Baltimore indicated that it wasn't working perfectly.

Q. If a system was set up and wasn't working, who was responsible for that, sir?

A. In Baltimore, I would hold Mr. McCahan responsible.

Q. Who set up the system, sir?

A. The organizational structure has been evolved over a good many years. Actually, I am responsible for the entire organizational structure.

Q. And if a system that is set up and it doesn't work, you are responsible for changing it, is that corect?

A. For any result which occurs in our company, I am ultimately the chief executive officer and, therefore, responsible.

The government's theory of the case, as stated in summation, was that "Mr. Park was responsible for seeing that sanitation was taken care of, and he had a system set up that was supposed to do that. This

system didn't work. It didn't work three times. At some point in time, Mr. Park has to be held responsible for the fact that his system isn't working * * *" (A. 60).

The district court instructed the jury on the issue of respondent's responsibility as follows (A. 61–62):

> The main issue for your determination is * * * whether the Defendant held a position of authority and responsibility in the business of Acme Markets.
>
> The corporation, Acme Markets, Incorporated, has already entered a plea of guilty to the charge placed against it, and, while that plea does not imply, in any way, the Defendant Park is guilty, the fact that the materials in question are foods held for resale after shipment in interstate commerce and held under unsanitary conditions are issues that are beyond question in the case and must be accepted by you.
>
> The statute makes individuals, as well as corporations, liable for violations. An individual is liable if it is clear, beyond a reasonable doubt, that the elements of the adulteration of the food as to travel in interstate commerce are present. As I have instructed you in this case, they are, and that the individual had a responsible relation to the situation, even though he may not have participated personally.
>
> The individual is or could be liable under the statute, even if he did not consciously do wrong. However, the fact that the Defendant is president[5] and is a chief executive officer of the Acme Markets does not require a finding of guilt. Though, he need not have personally participated in the situation, he must have had a responsible relationship to the issue. The issue is, in this case, whether the Defendant, John R. Park, by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose.[6]

[5] Although the transcript says "present," the court obviously meant, and presumably said, "president."

The jury found Park guilty on all counts.

B. THE DECISION OF THE COURT OF APPEALS

A divided panel of the court of appeals reversed. The majority believed the government to be arguing "that the conviction may be predicated solely upon a showing that the defendant, Park, was the President of the offending corporation" (Pet. App. 4A). The court held that "a finding of guilt must be predicated upon some wrongful action by Park. That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which could 'cause' the contamination of the food" (Pet. App. 5A–6A). The court concluded that Park's conviction must be reversed because the jury instruction "might well have left the jury with the erroneous impression that Park could be found guilty in the absence of 'wrongful action' on his part" (Pet. App. 5A).

[6] Counsel for Park submitted only two requests for charge:

(1) "Statutes such as the ones the Government seeks to apply here are criminal statutes and should be strictly construed," and (2) "The fact that John Park is President and Chief Executive Officer of Acme Markets, Inc. does not of itself justify a finding of guilty under Counts I through V of the Information." The latter of these, in substance, was given by the court (*supra*).

The court also held that evidence concerning the Philadelphia incident was unduly prejudicial and should not have been admitted (Pet. App. 8A). The court nevertheless suggested that the evidence might be admissible at retrial depending upon "the prosecution's new approach to the presentation of its case" (Pet. App. 9A) and the district court's application of the standards for admission of evidence of prior offenses set forth in *United States* v. *Woods*, 484 F. 2d 127, 134 (C.A. 4).

Judge Craven dissented on the ground that "this case is controlled by *United States* v. *Dotterweich*, 320 U.S. 277 (1943)" (Pet App. 9A). He explained (Pet. App. 10A):

> * * * Park was not just 'remotely entangled' in the proscribed adulteration. Like Dotterweich, he was president of the corporation with full power to control its operations and to take measures to prevent rat infestation of food. Although he had delegated the day-to-day supervision of sanitation to subordinates, Park retained both the power and responsibility to see that the system of rodent control was effective, and if it didn't work, to change it.

He noted that the government had made "no effort to equate the presidency of the corporation with the responsibility. Instead the government argued that Mr. Park was responsible because he had established a system of rodent control that did not work in March 1970, November 1971 and March 1972 and that even so he made no effort to change or improve the system" (Pet. App. 11A; footnote omitted). Finally, he stated that, if FDA is required to show that Park

"acted wrongfully," evidence of prior violations would clearly be admissible or FDA could not possibly sustain its new burden of proof (Pet. App. 12A).

INTRODUCTION AND SUMMARY OF ARGUMENT

The Federal Food, Drug, and Cosmetic Act of 1938 is "a principal example" of legislation imposing "the highest standard of care on distributors * * *" (*Smith* v. *California*, 361 U.S. 147, 152). "[T]o stimulate proper care" (*United States* v. *Balint*, 258 U.S. 250, 253) "distributors of food * * * [are made] the strictest censors of their merchandise" (*Smith* v. *California*, *supra*, 361 U.S. at 152).

This high standard of care, and correlative strict liability, is of crucial importance to the public health because the Act's criteria of criminal liability, embodied in the provisions at issue here, govern the distribution of drugs and medical devices as well as food, and the adulteration, contamination or mislabeling of such products may have fatal or other serious consequences. Accordingly, laws of the kind involved here punish not only willful violations but also "neglect where the law requires care, or inaction where it imposes a duty." *Morissette* v. *United States*, 342 U.S. 246, 255.

1. *United States* v. *Dotterweich*, 320 U.S. 277, establishes that individual corporate officers and employees, as well as corporations, may be convicted for doing or causing the acts prohibited in Section 301 of the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 331. In that decision, this Court also restated

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the standard of responsibility for the corporate officers and agents through whom corporations handling food and drugs must act: those standing in a responsible relation to the prohibited acts may be criminally liable for failure to take steps to prevent their occurrence, even though the officers are not aware of wrongdoing.

Because corporate officers having managerial, policy-making or supervisory functions "have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers * * *" (*United States* v. *Dotterweich, supra,* 320 U.S. at 285), they are under an affirmative duty to be informed about, and to correct, conditions that violate the Act. Such a corporate officer is made criminally responsible for insanitary conditions because, "if he does not will the violation, [he] usually is in a position to prevent it with no more care than society might reasonably expect and no more exertion than it might reasonably exact from one who assumed his responsibilities" (*Morissette* v. *United States, supra* 342 U.S. at 256).

While the liability created by the 1938 Act is strict, it is not vicarious. The limits of the principle appear in its articulaton: the corporate officer must stand in a responsible relation to the prohibited acts; a claim that he is "powerless" may "be raised defensively at a trial on the merits." *United States* v. *Wiesenfeld Warehouse Co.,* 376 U.S. 86, 91.

In sum, officials of the business entities which affect the public health are subject to the highest standard of public accountability. This standard has protected the public since the Pure Food and Drugs Act of 1906, 34 Stat. 768; it was carried forward in the 1938 Act,

and it has stood unchanged to this day. The decision of the court of appeals in this case, however, would lower this standard by requiring proof that the responsible corporate official took "wrongful action," by which the court meant an affirmative showing of acts of "gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' the contamination of the food" (Pet. App. 6A). As *Dotterweich* shows, however, a corporate official "causes" a violation of the Act whenever he stands in a "responsible relation" to the prohibited condition and fails to take action to prevent or correct it.

The error of the court of appeals in requiring affirmative "wrongful action" by a corporate official is compounded by the fact that the court has read its decision in this case as making actual knowledge of the specific facts concerning a violation an element of responsibility. In *United States* v. *Abbott Laboratories,* C.A. 4, No. 74–1230, decided October 2, 1974, petition for a writ of certiorari pending, No. 74–699, the court, citing its decision in this case, stated that individuals who shared "in the responsibility of distributing adulterated or misbranded drugs in interstate commerce are potentially criminally liable" (slip op., p. 20).[7] The court then explained (*ibid.*):

[7] *Abbott* involved a criminal prosecution under Section 301 of the Act against Abbott Laboratories and five of its employees. The district judge dismissed the indictment because he believed there was prejudicial pretrial publicity and because he believed the grand jury was exposed to "prejudicial and inflammatory" information (slip op., p. 18). This court of appeals reversed.

> "Responsibility" in turn depends upon knowledge, and if knowledge is established it depends further on the action or non-action of the officer or employee after he has obtained knowledge.

This interpretation is contrary to *Dotterweich,* for, as the court of appeals recognized in this case, under *Dotterweich* "21 U.S.C. §§ 301–392 'dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing'" (Pet. App. 4A, quoting 320 U.S. at 281).

The legislative history confirms *Dotterweich's* interpretation of the 1938 Act. The criminal provisions of the Pure Food and Drugs Act of 1906 did not require proof of either knowledge or intent. This standard of criminal liability was carried forward in the 1938 Act, which was designed "to enlarge and stiffen the penal net." *Dotterweich, supra,* 320 U.S. at 282. Indeed in 1948, after *Dotterweich* had been decided, Congress explicitly rejected an attempt to limit criminal liability to offenses committed "willfully or as a result of gross negligence."

Congress and this Court in *Dotterweich* recognized that the strict standard of liability of the 1938 Act could operate harshly, or even unfairly, and that FDA should therefore exercise reasonable discretion in pursuing criminal prosecutions. It has, accordingly, been FDA policy to limit prosecutions to continuing violations, violations of an obvious or flagrant nature, and intentionally false or fraudulent violations. Prosecution of individual corporate officials is confined to those in a "responsible relation" to the offense; that is, officials who have the power and responsibility to prevent or discover and correct violations and fail to do so.

The prosecution of Acme and Park was in conformity with these guidelines. The rodent infestation of the Baltimore warehouse was a serious and continuing violation. Moreover, Park, although not required by *Dotterweich,* had actual notice from FDA of the problem and failed to correct it.

The decision below, limiting the liability of corporate officials to cases of "wrongful action," would seriously undermine Congress' efforts to protect the public health by imposing criminal liability on distributors of adulterated food and drugs, without regard to wrongful acts or knowledge of violations, "in order to stimulate proper care * * *." *United States* v. *Balint, supra,* 258 U.S. at 253. That interpretation would, moreover, tend to defeat the purpose of Congress by inviting corporate executives to insulate themselves from active supervision of matters vitally affecting the public health. Moreover, the standard adopted by the court of appeals would impose an unrealistic and impractical burden of proof on the government, since, even where an official knows of the problem in general terms, it may be impossible to prove that he knew of the actual contamination of a particular lot of food.

2. The evidence of prior insanitary conditions in the Philadelphia warehouse was admissible to rebut Park's defense that he justifiably relied on his subordinates. Since the same subordinates were involved in the Philadelphia violation, the April 1970 letter to Park tended to show that he had prior notice that his

subordinates were not taking adequate measures to prevent and correct insanitary conditions.

ARGUMENT

I. THE FOOD, DRUG, AND COSMETIC ACT IMPOSES CRIMINAL LIABILITY ON CORPORATE OFFICIALS WITH A "RESPONSIBLE RELATION" TO SANITATION WHO FAIL TO TAKE AFFIRMATIVE ACTION TO PREVENT INSANITARY CONDITIONS

A. UNDER THIS COURT'S DECISIONS, THE ACT IMPOSES CRIMINAL LIABILITY ON RESPONSIBLE CORPORATE OFFICIALS WHO FAIL TO PREVENT INSANITARY CONDITIONS, EVEN IN THE ABSENCE OF DELIBERATE WRONGDOING

Congress' intention to impose strict criminal liability for violations of Section 301, 21 U.S.C. 331, is apparent in the Act's penalty provisions. Section 303(a) makes a first violation of Section 301 a misdemeanor; Section 303(b) makes either a second violation, or a violation committed "with the intent to defraud or mislead," a felony. Section 303(c) provides for immunity in certain cases, not including insanitary warehouse conditions, in which goods have been received or delivered in good faith. 21 U.S.C. 333(a), (b) and (c). The fact that a first offense with intent to defraud or mislead is subject under Section 303(b) to heavier penalties than are prescribed under Section 303(a) for a first offense without such intent, shows that wrongful action and knowledge are not elements under Section 303(a). See S. Rep. No. 493, 73d Cong., 2d Sess., p. 20 (discussed *infra,* p. 28). Similarly, the carefully defined conditions under which good faith establishes immunity under Section 303(c) strongly indicate a legislative purpose to impose liability, notwithstanding good faith, in all other cases falling under Section 303(a). This interpretation was confirmed by this Court in *United States* v. *Dotterweich, supra,* and reaffirmed in *United States* v. *Wiesenfeld Warehouse Co.,* 376 U.S. 86, 91.

The *Dotterweich* case involved prosecution under Section 301 of a drug jobbing corporation, and its president and general manager, Dotterweich, for shipping misbranded and adulterated drugs in interstate commerce. A jury failed to convict the corporation, but nevertheless convicted Dotterweich as the responsible corporate officer even though he had no personal knowledge of the misconduct involved.[8] Despite the plain language of the statute, the court of appeals set aside the conviction, reasoning that liability should be confined to the corporation as a proprietor, and should not be extended to the individual agents through which it acts, because only the corporate principal could obtain a guaranty from its suppliers that their products were not adulterated or misbranded.[9] *United States* v. *Buffalo Pharmacal Co.,* 131 F. 2d 500 (C.A. 2).

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[8] The defendant was not personally involved in any of the shipments in question and had no knowledge of them when they were made. He did not examine any drug orders when they were received because these orders were processed automatically by his firm's shipping department according to established company procedures. The defendant was in general charge of the business, however, and was responsible for the firm's system of operations (Record On Appeal No. 44-2841, O.T. 1943, pp. 128-129, 144, 159).

[9] Such a guaranty, received in good faith, establishes immunity under Section 303(c), 21 U.S.C. 333(c).

This Court reversed the judgment of the court of appeals and reinstated Dotterweich's conviction. It held that the liability defined by the statute was not limited to corporations or other proprietors in a position to obtain immunity through the guaranty provisions of Section 303(c). On the contrary, the statute "casts the risk that there is no guaranty upon all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor." 320 U.S. at 284.

The Court explained that the Act "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in a responsible relation to a public danger. *United States* v. *Balint,* 258 U.S. 250." 320 U.S. at 281.

The 1938 Act makes responsible corporate officials criminally liable for failure to discover and correct insanitary conditions because they have the power and responsibility to prevent such conditions, and have failed to do so. The imposition of this strict standard of liability is based on the fact that responsible corporate officials have at least the opportunity to learn of, correct or prevent, insanitary conditions, whereas even the most scrupulous careful consumer is helpless against them. As the Court explained in *Dotterweich, supra,* 320 U.S. at 284–285:

> Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who

> have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

See also *Morissette* v. *United States, supra,* 342 U.S. at 256.[10]

Thus certain corporate officials are under a duty to seek out and prevent insanitary conditions, and are made criminally liable for "inaction where * * * [the law] imposes a duty" (*id.* at 255). The duty thus imposed was intended to make "the distributors of food the strictest censors of their merchandise * * *" (*Smith* v. *California, supra,* 361 U.S. at 152). It requires the responsible officials to keep informed as to conditions which might violate the act, and bars them from claiming ignorance as a defense when violations within their zone of responsibility occur. See *United States* v. *Balint, supra,* 258 U.S. at 252–253; *Smith* v. *California, supra,* 361 U.S. at 152.

This duty is imposed only upon those "standing in responsible relation to a public danger," *United States* v. *Dotterweich, supra,* 320 U.S. at 281. This criterion limits the liability of corporate officials to those individuals whose functions within the corporation impose on them a duty to be informed, and who have power to initiate preventive measures or to order corrections.

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[10] The Court has subsequently relied upon *Dotterweich* not only in *Wiesenfeld, supra,* 376 U.S. at 91, but also in *United States* v. *Freed,* 401 U.S. 601, 609, in which it upheld the standard of criminal liability imposed by the National Firearms Act.

In *Dotterweich* the Court characterized the responsible relationship as follows (320 U.S. at 284): "The offense is committed, unless the enterprise which they are serving enjoys the immunity of a guaranty, by all who do have * * * a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs." The Court explained, however (*ibid.*): "Whether an accused shares a responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance." The Court added (*id.* at 285): "In such matters the good sense of the prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted."

The concept of responsible relation thus serves to limit the application of the Act to those corporate officials who have the power and responsibility to prevent or correct insanitary conditions, but fail to do so. The same objective is served by allowing an apparently responsible corporate official to prove—as a matter of defense—that he is without power to affect the prohibited condition. This is shown by *United States* v. *Wiesenfeld Warehouse Co., supra,* in which a warehouse company was charged under Section 301 (k) with holding food under conditions similar to those charged in the instant case. The defendant argued that the government was "seeking to impose criminal sanctions upon one 'who is, by the very nature of his business powerless' to protect against this kind

of contamination, however high the standard of care exercised." 376 U.S. at 91. The Court held: "Whatever the truth of this claim, it involves factual proof to be raised defensively at a trial on the merits" (*ibid.*).

Thus, under *Dotterweich* and *Wiesenfeld,* whether an individual bears a "responsible relation" to the offense is for the jury to determine in the light of his functions within the corporation and such defensive matters as he may raise at trial bearing on his power with respect to the violation.

The holding of the court of appeals in the present case would substantially distort this statutory scheme. The court recognized that under the Act the government need not prove "awareness of some wrongdoing" (Pet. App. 4A, quoting *Dotterweich,* 320 U.S. at 281). However, the court concluded that in prosecuting Park, as the responsible corporate officer, "the Government has confused the element of 'awareness of wrongdoing' with the element of 'wrongful action;' *Dotterweich* dispenses with the need to prove the first of those elements but not the second" (Pet. App. 4A; footnote omitted). And, noting that Section 301(k) prohibits "causing" adulteration, it defined " 'wrongful action' in this context as acts of the accused which *cause the* adulteration of such food" (Pet. App. 4A, n. 4; emphasis in original).

As *Dotterweich* shows, however, a corporate official "causes" a violation of the Act whenever he stands in a "responsible relation" to the prohibited condition and fails to take action to prevent or correct it. He may violate the Act by "inaction where it imposes a

duty" (*Morissette* v. *United States, supra,* 342 U.S. at 255); affirmative "wrongful action" by the accused is not required.

The jury instructions in *Dotterweich,* which were approved by this Court (320 U.S. at 285), clearly show that proof of a wrongful act by a corporate official is not necessary to establish his liability under Section 301.[11] These instructions did not require the jury to find "wrongful action" by the defendant, but simply to determine responsibility. Similarly, the charge in the instant case instructed the jury to determine whether Park "had a position of authority and responsibility in the situation out of which these charges arose." Statement, *supra,* p. 10–11.

As Judge Craven recognized in dissenting below, the government has never argued that Park is guilty of violating Section 301 solely because he is president of the corporation. And the trial judge carefully noted in his instructions (Statement, *supra,* p. 10–11). that corporate titles do not necessarily prove

[11] The district court in the *Dotterweich* case instructed the jury as follows:

"We also have as a defendant here, Joseph Dotterweich. As far as the question of his guilt regarding the charges in the information is concerned, the question is, if you find the product to be misbranded and adulter'ed, 'Was he responsible for the shipment of them in interstate commerce?' In other words, are you satisfied from the evidence that the shipment of the cascara compound and the shipment of the digitalis were made under his supervision by him as 'General Manager.' It is not necessary for the Government to prove that he personally and physically made the shipment himself. It is sufficient if the evidence establishes to your satisfaction that it was made under authority conferred by him as general manager upon his subordinates, including the receiving and shipping clerk." Record on Appeal No. 44–2841, O. T. 1943, p. 164. See, also, *United States* v. *Kaadt,* 171 F. 2d 600, 604 (C.A. 7).

responsibility for the situations resulting in violation of the Act. Rather, the government must offer proof of actual supervisory responsibility relating to the prohibited conditions. It was for the jury to determine in the light of that proof and the defendant's exculpatory evidence whether he was in fact responsible.

The error of the court below in requiring proof of "wrongful action" by the defendant is compounded by that court's subsequent decision in *United States* v. *Abbott Laboratories, supra.* In its decision in the present case, the court at least purported to recognize that the 1938 Act "dispenses with * * * awareness of some wrongdoing" (Pet. App. 4A). In *Abbott Laboratories,* however, the court held that "responsibility" under the Act "depends upon knowledge, and * * * on the action or nonaction of the officer or employee after he has obtained knowledge" (slip op., p. 20). In this more recent explication of its view of the 1938 Act, the court of appeals has, in effect, repudiated the holding of *Dotterweich, supra.*

Dotterweich defines standards of corporate and individual responsibility which are fundamental in the food and drug industries. They have been applied in numerous cases. For example, in *United States* v. *H. B. Gregory Co.,* 502 F. 2d 700 (C.A. 7), petition for a writ of certiorari pending, No. 74–142, the Court of Appeals for the Seventh Circuit expressly rejected a contention that the strict and personal liability defined by *Dotterweich* was an improper legal standard because it "fails to require a casual relation between the individual and the violation of the Act." 502 F. 2d at 705. Accord, *United*

States v. *Shapiro*, 491 F. 2d 335–337 (C.A. 6); *Lelles* v. *United States*, 241 F. 2d 21, certiorari denied, 353 U.S. 974; *United States* v. *Cassaro Inc.* 443 F. 2d 153, 157 (C.A. 1); *United States* v. *Kaadt*, 171 F. 2d 600 (C.A. 7); *United States* v. *Parfait Power Puff Co.*, 163 F. 2d 1008 (C.A. 7), certiorari denied, 332 U.S. 851; *United States* v. *Diamond State Poultry Co.*, 125 F. Supp. 617 (D. Del.).

B. THE LEGISLATIVE HISTORY CONFIRMS THIS COURT'S INTERPRETATION OF THE 1938 ACT

The standard of care and the criteria of criminal responsibility enunciated in *Dotterweich* and *Wiesenfeld* are those intended by Congress. That *Dotterweich* correctly construed the 1938 Act may be seen both from the legislative history of that Act and from Congress' actions subsequent to *Dotterweich*.

The first general federal statute prohibiting the adulteration and misbranding of foods and drugs, the Pure Food and Drug Act of 1906, established a strict standard of criminal liability. The criminal provision of the 1906 Act did not require proof of either knowledge or intent as an element of the criminal offense, and numerous cases held that it was intended to impose strict criminal liability upon both corporations and individuals.[12]

[12] See, e.g., *United States* v. *36 Bottles of London Dry Gin*, 210 Fed. 271 (C.A. 3); *Von Bremen* v. *United States*, 192 Fed. 904 (C.A. 2); *United States* v. *Mayfield*, 177 Fed. 765 (D. Ala.); *United States* v. *Buffalo Cold Storage Co.*, 179 Fed. 865 (W.D.N.Y.). See, generally, cases collected in White and Gates, *Decisions of Courts in Cases under the Federal Food and Drugs Act* (1934).

Despite this strict standard of liability, Congress began its work on the 1938 Act with an express concern that the penalties imposed under the 1906 Act had failed to secure compliance with the law. As the 1934 Senate Report on S. 2800 stated (S. Rep. No. 493, 73d Cong., 2d Sess., p. 20):

> The penalties provided under the present Food and Drugs Act have proved wholly inadequate to bring about substantial compliance with the law on the part of those manufacturers who regard an occasional small fine as an inexpensive license to carry on their illicit operations.[13]

Thus the 1938 Act was designed "to enlarge and stiffen the penal net." *United States* v. *Dotterweich*, *supra*, 320 U.S. at 282.

Congress' discussion of the penal provisions of the 1938 Act make it clear that the strict standard of liability in the 1906 Act was carried forward in the

[13] The original version of what eventually became the 1938 Act, S. 1944, 73d Cong., 1st Sess., and a similar bill, S. 2800, 73d Cong., 2d Sess., were initially referred to the Senate Committee on Commerce for hearings. After a series of hearings and a report, S. Rep. No. 493, 73d Cong., 2d Sess., the proposed legislation was revised and further hearings were held in both Houses of Congress. Meetings were also held with various representatives of the food, drug and cosmetic industries. After more than three years of congressional hearings, floor debates and discussions with consumer and industry representatives concerning various bills and proposals, committees in both Houses filed reports recommending adoption of S. 5, 75th Cong., 1st Sess. See S. Rep. No. 152, 75th Cong., 1st Sess.; H. Rep. No. 2139, 75th Cong., 3d Sess. After differences between the House and Senate versions of the bill were resolved by a Conference Committee, the bill was enacted into law. The legislative history of the 1938 Act is contained in Dunn, *Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record* (1938).

new law. Thus, the Senate Report on S. 2800 stated (S. Rep. No. 493, 73d Cong., 2d Sess., p. 20):

> Under the existing law the willful violator stands on the same plane with the party who inadvertently violates the law through the negligence of his employees. Paragraph (c) will place willful violators in a special category subject to heavier penalties than those who violate the law through inadvertence, carelessness, or negligence.

Though the proposal that eventually became the 1938 Act was revised substantially during the years it was pending before Congress, the distinction, adverted to in the Senate Report, between the penalties for willful and nonwillful violations, was retained in the final bill. The legislative history of these provisions thus establishes that Congress intended to continue to impose criminal liability on corporate officials for violations of the Act, even if they did not personally order or personally commit the offense.[14]

[14] The Senate Commerce Committee deleted from section 2(f) of S. 5, 75th Cong., 1st Sess., language which would have limited criminal liability to corporate officers "who personally ordered or did any of the acts constituting, in whole or in part * * *" violations of the Act. See Dunn, *Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record*, p. 657 (1938). Although the committee did not specifically explain why it deleted this particular language (see S. Rep. No. 91, 75th Cong., 1st Sess.; S. Rep. No. 152, 75th Cong., 1st Sess.), it is reasonable to infer that Congress intended to impose a standard of criminal liability on corporate officers at least as broad as that recognized in the 1906 Act. *See Dotterweich*, *supra*, 320 U.S. at 282.

Congress also deleted, as unnecessary, Section 12 of the 1906 Act which provided that "the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person." (*Id.* at 281–282) As the Court said in *Dotterweich*, *supra*, 320 U.S. at 282, "By 1938, legal understanding and practice had rendered such statement of the obvious superfluous."

Following this Court's decision in *Dotterweich*, hearings were held in Congress at which it was suggested that some proof of knowledge or intent should be required before criminal sanctions could be imposed.[15] This suggestion was opposed not only by FDA and various members of Congress but also by Mr. Charles Wesley Dunn who testified on behalf of the Grocery Manufacturers of America, the American Pharmaceutical Manufacturers Association and the New York State Bar Association. He stated:

> It has always been the situation under the Food and Drug law, and the law of unfair competition in the Federal Trade Commission Act, that intent is not an essential ingredient of the offense. If you make it so, you simply nullify, in effect, the practical value of these laws.

Hearings before a subcommittee of the Senate Committee on Interstate and Foreign Commerce on S. 1190 and H.R. 4071 80th Cong., 2d Sess., p. 49. Mr. Dunn added that to "reverse the traditional policy of the Food and Drug law of this country by making intent an essential ingredient of the offense * * * would emasculate this law * * *" (*ibid.*). Moreover, Mr. Dunn commented

[15] See, *e.g.*, Hearing before a Subcommittee of the Senate Committee on Interstate and Foreign Commerce, on S. 1190 and H.R. 4071, 80th Cong., 2d Sess., pp. 70–71.

"That is good" when Senator McMahon quoted a pertinent excerpt from the Court's opinion in *Dotterweich* during the hearings (*id.* at 49–50).

Nonetheless after these hearings the Senate passed a bill amending Section 303(a) of the Act to impose criminal liability only for violations committed "willfully or as a result of gross negligence." 4 Cong. Rec. 6760–6761 (June 1, 1948). However, the amendment was subsequently stricken in conference. 94 Cong. Rec. 8551 (June 17, 1948); 94 Cong. Rec. 8838 (June 18, 1948). Thus, Congress specifically refused to alter the standard of criminal liability imposed by the 1938 Act as construed by this Court in *Dotterweich*. It remained unchanged until the decision of the court of appeals in the present case.

C. THE 1938 ACT CONTEMPLATES REASONABLE EXERCISE OF PROSECUTORIAL DISCRETION IN ITS ADMINISTRATION

In enacting the 1938 Act Congress recognized that the strict standards of liability created might operate harshly, or even unfairly. Congress therefore expressed its concern that minor violations of the Act should not be subjected to criminal prosecution. Thus, Section 306 of the Act, 21 U.S.C. 336, provides that:

> Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

This provision indicates that FDA was expected to exercise reasonable discretion in invoking the Act's

criminal sanctions. Accordingly, the Court observed in *Dotterweich* that fair enforcement of the Act "must be trusted" in part to "the good sense of prosecutors." 320 U.S. at 285.

In exercising the reasonable prosecutorial discretion contemplated by Congress and this Court, FDA has applied criteria which do not result in criminal prosecutions for every violation of the statute's strict standard of criminal liability. The government is interested in the prevention and correction of conditions potentially dangerous to the public health and welfare, not in prosecution for its own sake. Accordingly, FDA's standards for reference of cases to the Department of Justice for prosecution embrace the following categories: continuing violations of law (*e.g.*, continuing insanitary conditions in a food plant); violations of an obvious and flagrant nature (*e.g.*, food warehouse overrun with rodents, birds and insects, which contains plainly contaminated products); and intentionally false or fraudulent violations.

The standard for prosecution of individual corporate officials, as distinguished from the prosecution of their corporations, is based on the reasonable relationship criterion of *Dotterweich*. The government's policy is to prosecute only those individuals who are in a position and who have an opportunity to prevent or correct violations, but fail to do so. Officials who lack authority to prevent or correct violations, or who were totally unaware of any problem and could not have been expected to be aware of it in the reasonable exercise of their corporate duties, are not the subject of criminal action. Even if investigation discloses the ele-

ments of liability, and indicates that an official bears a responsible relationship to them, the agency will not ordinarily recommend prosecution unless that official, after becoming aware of possible violations, often (as with Park) as a result of notification by FDA, has failed to correct them or to change his managerial system so as to prevent further violations.[16] In those instances where prosecution is brought, it is brought for past, as well as most recent, violations.

D. THE PROSECUTION OF PARK WAS REASONABLE AND HIS CONVICTION IS SUPPORTED BY THE EVIDENCE

The government's decision to prosecute Park personally, as well as Acme, was in conformity with the guidelines just discussed. The massive rodent infestation of Acme's warehouses is scarcely a minor or technical violation of the 1938 Act. It is a potential health hazard.[17] As FDA stated to Park in its letter of January 1972, the "reprehensible conditions [of the Baltimore warehouse] obviously existed for a prolonged period of time without any detection, or were completely ignored" (A. 64).

[16] FDA has adopted an elaborate system of internal review and enforcement guidelines, and also offers a hearing, even though one is not required, so that suspects can explain the situation before a prosecution is recommended. The review requires approval by the FDA Regional Directors, the compliance division of the relevant bureau (e.g., Bureau of Foods), the Regulatory Management Staff in the office of the Associate Commissioner for Compliance and the Assistant General Counsel, Food and Drugs Division, Department of Health, Education, and Welfare.

[17] The hazard of insanitary food storage is indicated by the following observation in Levy and McIntire, *The Economic Impact of a Food-Borne Salmonellosis Outbreak*, American Medical Association Journal, Vol. 230, No. 9 (December 2, 1974), p. 1281:

"Approximately five food-borne disease outbreaks of this size [125 persons] and numerous other cases of food-borne illness, are reported and investigated every year in Minnesota. In addition, many other cases are thought to go unrecognized as food-borne illness or to be recognized but not reported to health departments. The total economic loss from this food-borne illness no doubt amounts to hundreds of thousands of dollars a year. Greater expenditure for effective preventive measures, at relatively low costs, could have dramatic effects on reducing the occurrence of food-borne illness and its considerable economic impact."

Moreover, Park personally had received a letter from FDA in April 1970 advising him of serious rodent infestation in Acme's Philadelphia warehouse (A. 70–71). And in its letter of January 27, 1972, FDA informed Park of the unwholesome conditions revealed in the Baltimore warehouse by the November–December 1971 inspection.[18] Park nevertheless failed to take adequate steps to correct these conditions. After merely being generally assured by another subordinate in January 1972 that Mr. McCahan would take corrective action, Park concluded that there was nothing more he could have done constructively (A. 47). He simply passed FDA's report on to his subordinates, as if he had no personal responsibility to require effective measures to put an end to the serious

[18] The November-December 1971 inspection revealed, among other things, that the warehouse was heavily infested with rodents, buildings were open to rodent and bird entry due to poor fitting and damaged doors and broken windows; trash and damaged merchandise was found between and behind stored food; food was stored against walls and so close together that inspection was difficult or impossible; stock was not rotated and lighting was so insufficient in some areas that employees could

existing violations of the Act that had been brought to his attention.[19]

Although his subordinates took steps that partially corrected these conditions (A. 23), the agency's March

not see defiled merchandise; and that, as a result of these and other insanitary conditions, 150,000 lbs. of food products were rodent-defiled and had to be destroyed (see *supra*, pp. 4–5).

[19] There were a number of constructive actions he should have taken. With the list of observations before him, he could have applied his own common sense to the situation and personally ordered corrective action. He could have, for instance, demanded that the warehouse be completely emptied and cleaned, that each lot of food be moved and checked thoroughly for rodents, and that the structure be thoroughly checked to make sure that all possible points of rodent entry be closed. Such measures are elementary methods of housecleaning.

At the very least, respondent should have personally discussed with McCahan the list of observations item by item and ascertained precisely what McCahan would do about each. He could have demanded to know why the Baltimore facility had been allowed to deteriorate to the point that it had. He could have attempted to ascertain the amount of effort and money that would be necessary to insure that the premises would be cleaned up properly and offered McCahan whatever assistance was necessary. Any one or all of these things would have impressed upon McCahan the importance which he attached to the situation. He could also have instructed the appropriate corporate officials to utilize the resources necessary to remedy the situation. Certainly respondent could have followed up by calling McCahan and other corporate officials who handled sanitation problems to get personal briefings on the specific corrections being made. Indeed, given the fact that these same employees had already failed twice in the recent past, respondent could have retained a reputable outside consultant familiar with FDA requirements. Nor would it have been unreasonable for respondent to have personally visited the Baltimore warehouse to see for himself what progress, if any, was being made in correcting the situation. Finally, he could have closed the warehouse down unless and until he was personally satisfied that it had, beyond any doubt, been cleaned up. Given respondent's apathetic behavior, it is not surprising that the necessary steps were not taken and that many of the conditions went uncorrected until a criminal prosecution was instituted.

1972 inspection revealed that serious sanitation problems continued to exist in the Baltimore warehouse. Only then did FDA recommend prosecution of Park, as well as the corporation, for the specific violations found in November and December 1971 and in March 1972.

The evidence warranted Park's conviction. Park acknowledged that, as Acme's chief executive officer, he was "responsible for the entire organizational structure" and he agreed with the prosecutor's statement that "if a system that is set up and it doesn't work, you are responsible for changing it" (A. 55). Park was advised in April 1970 (with respect to the Philadelphia warehouse) and again in January 1972 (with respect to the Baltimore warehouse) that his system for controlling sanitation problems had failed, and Park conceded that "the fact that this occurrence occurred in Baltimore indicated that it wasn't working perfectly" (A. 55). In these circumstances, the jury was justified in concluding that Park bore a "responsible relation" to the insanitary conditions of the Baltimore warehouse.

E. THE COURT OF APPEALS' STANDARD WOULD TEND TO DEFEAT THE PUBLIC HEALTH PURPOSE OF THE ACT'S CRIMINAL PROVISIONS

The 1938 Act imposes "the highest standard of care on [food] distributors," because "the public interest in the purity of its food is so great" (*Smith* v. *California, supra,* 361 U.S. at 152). Despite these stringent

standards, insanitary conditions in the food industry remain a serious problem. Indeed, more than 90 percent of the legal actions brought by FDA under the 1938 Act concern insanitary conditions in food establishments. Notwithstanding these efforts, in a 1972 special report to Congress the General Accounting Office concluded that sanitary conditions in the food industry in the United States were deteriorating. It found in a survey limited to manufacturing and processing establishments that, as of 1972, 40 percent of the plants surveyed were operating under insanitary conditions, and 24 percent were seriously insanitary. It recommended an increase in FDA's enforcement effectiveness.[20] In response, Congress has substantially increased FDA appropriations for food establishment inspection and enforcement.

The lower standards of public accountability adopted by the court of appeals in the present case would seriously impair FDA's efforts to correct this serious problem and would substantially frustrate the purpose of the 1938 Act. To be effective against the growing problem of insanitary conditions the law must be effective against supermarket chains, such as Acme. Supermarket sales in the United States in 1973 exceeded 56.3 billion dollars. And supermarket chain stores accounted for 49.8 percent of all supermarket sales in that year. Among supermarket chains in the United States, Acme is the fourth largest with sales in 1973 exceeding 2.3 billion dollars. See *Progressive Grocer*, April 1974; see also, National Commission on Food Marketing, *Organization and Competition in Food Retailing* (1966).

[20] Comptroller General of the United States, *Dimensions of Insanitary Conditions in the Food Manufacturing Industry*, Report to the Congress, No. B–164031(2) (April 18, 1972).

Yet the holding below would weaken the law in relation to large corporate entities such as supermarket chains by making the prosecution of responsible corporate officials more difficult. Prosecution of such large corporations without the inclusion of responsible individuals has relatively little deterrent effect.[21] It is precisely because responsibility may be disbursed and diluted within a large firm's bureaucracy that the statute imposes liability on senior corporate officials in order to motivate them to anticipate and prevent problems or to seek them out and have them corrected. See discussion, *supra*, p. 20–23 The holding below, however, by requiring "wrongful action," and (under *Abbott*) knowledge of it, would encourage individual corporate officials to avoid knowledge and to insulate themselves from information that might show a violation of the law. High corporate officials, best situated to require preventive measures, would be encouraged to delegate

[21] See, *e.g.*, the National-American Wholesale Grocers' Association, *Warehouse Sanitation Manual* 106 (1972 ed.):

"A. A TOTAL COMMITMENT BY TOP MANAGEMENT

"This is the obvious and absolute must. Nothing less than a total commitment will suffice * * *.

* * * because it is top management whose neck is on the chopping block should the FDA axe fall;

* * * because a no-nonsense sanitation policy can only be effected and perpetuated down through the ranks if it has the top man's full sanction, personal involvement, and complete support."

their responsibility to lower officials, and those individuals would in turn undoubtedly seek to place the responsibility elsewhere. By contrast, the Act's strict standard of criminal liability, properly applied here by the district court, gives executives a personal incentive to seek out the problems within the company and to have them corrected.

Moreover, the court of appeals' standard would place an impractical burden of proof on the government. Even where a corporate official knows, in general terms, about a problem of insanitary conditions in a food warehouse, he is unlikely to know about any of the details, and thus may not knowingly or willfully have caused the specific violations involved. Even the local warehouse manager would not necessarily know that a particular lot of flour or breakfast cereal was contaminated, even though he might very well know about the general insanitary conditions of the warehouse. Unless a standard of strict criminal liability is imposed, therefore, in most instances, the very officials responsible for maintaining compliance with the law, and who possess the corporate authority to assure compliance, would simply escape liability for lack of detailed proof.

The larger the enterprise, the less effective would the government's enforcement capabilities become. In order to assure the high degree of accountability envisioned by Congress when the law was enacted, strict criminal liability is even more important today than it was in 1938, when the food industry was characterized by smaller firms.

Finally, as we have noted (*supra,* p. 13), the strict standards of the 1938 Act, as interpreted by *Dotterweich,* are of pervasive importance to the public health because the same standards of care and the same penal provisions at issue here govern the distribution of life-threatening and life-saving drugs and medical devices, as well as food.

II. EVIDENCE OF PRIOR INSANITARY CONDITIONS AT ANOTHER WAREHOUSE WAS ADMISSIBLE TO REBUT PARK'S DEFENSE OF GOOD FAITH RELIANCE ON HIS SUBORDINATES

In its case-in-chief the government established that Acme's system of sanitation control required the cooperation of several different corporate officials and that Park was responsible for seeing that all these individuals worked together. See testimony of Dr. Norman Kramer (A. 30–34); Robert McCahan (A. 34–39); and A. E. Gilfillan (A. 39–42). See also Statement, *supra.*

Park testified in his own defense that he had employed a system in which he relied upon his subordinates, and that he was ultimately responsible for this system. He further testified that he had found these subordinates to be "dependable" and had "great confidence" in them (A. 49; Tr. 166). Accordingly, the jury might have inferred from Park's testimony that his subordinates, and not he, should be held responsible since the sanitation duties had been delegated to them and he had no reason to suspect they were failing to get the job done.

On cross-examination, the government established that twenty months before discovery of the insanitary

conditions at the Baltimore warehouse, FDA had sent a letter to Park advising him of insanitary conditions at the firm's Philadelphia warehouse. The purpose of this line of questioning was to show that Park was on notice that he could not rely upon his system of delegation to subordinates to prevent insanitary conditions at the firm's warehouses and that he was aware of the deficiencies of this system before the Baltimore violations were discovered. Park admitted that he had the responsibility and the power to take whatever steps were necessary to insure that the firm's system for handling sanitation problems worked in compliance with the Act (A. 54–55).

The court of appeals viewed this evidence as if it were evidence of an unprosecuted prior crime, the admissibility of which depended on a balancing of prejudice to the defendant against the needs of justice. See *United States* v. *Woods, supra,* 484 F. 2d at 134–135.[22] It found that the evidence was prejudicial and that no need for it had been shown under the theory on which the case was tried. The evidence demonstrated, however, both Park's awareness of prior sanitation deficiencies in Acme's warehouse system and his admitted responsibility for correcting them. This testimony was therefore relevant to the issue of Park's "responsible relationship" to the violations since it served to rebut his defense that he had justifiably

[22] In *Woods*, the defendant was charged with first degree murder of an infant. The court held that evidence that other children in her care had died or had suffered respiratory problems was admissible to prove that the crime charged had in fact been committed.

relied upon subordinates to handle sanitation matters.

This testimony was not offered by the government during its case in chief; it was elicited from Park in response to his testimony on direct examination. Such a procedure is appropriate when a defendant "introduces evidence in his own behalf after his motion for acquittal has been overruled." *United States* v. *Calderon,* 348 U.S. 160, 164. For example, in *United States* v. *Ross,* 321 F 2d 61, 67 (C.A. 2), certiorari denied, 375 U.S. 894, the defendant in a prosecution for securities fraud testified on direct examination that he was "an unwitting tool" in the fraud. The court held that the government could elicit testimony on cross examination establishing that the defendant "had long drifted among [brokerage] houses selling similarly worthless stock by similar methods." *Id.* at 67. See also, *United States* v. *Kaufman,* 453 F. 2d 306 (C.A. 2); *United States* v. *Purin,* 486 F. 2d 1363 (C.A. 2), certiorari denied, 417 U.S. 930; *United States* v. *Wright,* 466 F. 2d 1256 (C.A. 2), certiorari denied, 410 U.S. 916.[23]

The testimony concerning the sanitation problem at the Philadelphia warehouse was not offered to show that Park had a propensity to commit criminal acts or, as in *United States* v. *Woods, supra,* to show that

[23] Cf. *Walder* v. *United States*, 347 U.S. 62 (evidence of prior arrest for possession of narcotics admissible to impeach defendant's testimony); *Michelson* v. *United States*, 335 U.S. 469 (a defense character witness may be cross-examined concerning his knowledge of defendant's prior criminal activities); *Williamson* v. *United States*, 207 U.S. 425 (evidence of prior criminal acts admissible to establish guilty intent, design, purpose or knowledge).

the crime charged had been committed. Rather it was offered to show that Park's alleged reliance on his subordinates could not have been justifiable. This testimony was therefore directly relevant to the jury's determination of whether respondent shared the responsibility for the insanitary condition of the firm's Baltimore warehouse.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the judgment of the court of appeals should be reversed.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

UNITED STATES OF AMERICA, Petitioner

v.

JOHN R. PARK

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

BRIEF FOR RESPONDENT

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BRIEF FOR RESPONDENT

OPINIONS BELOW

The opinions in the court of appeals (Pet. App. 1A-12A) are reported at 499 F.2d 839.

JURISDICTION

The judgment of the court of appeals was entered on July 2, 1974 (Pet. App. 13A). On July 26, 1974, Mr. Chief Justice Burger extended to August 31, 1974, the time within which to file a petition for a writ of certiorari.

The petition was filed on August 30, 1974, and granted on November 11, 1974 (A. 73). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

QUESTIONS PRESENTED

1. Whether, in a prosecution of a corporate officer for doing or causing acts resulting in the adulteration of food, the instructions to the jury were proper under the statute as construed in *United States* v. *Dotterweich*, 320 U.S. 277, when:

(a) the jury was twice instructed that the issue for their determination was whether the individual defendant held a position of authority and responsibility in the business of the corporation of which he was president; and

(b) the jury was never instructed to determine whether the individual defendant was responsible for the doing or causing of the acts charged in the information.

2. Whether, upon a subsequent trial, instructions should be given that for an accused individual to be found guilty on charges of doing or causing acts resulting in adulteration of food:

(a) the jury must find that he was personally responsible for the acts constituting the crimes charged, and

(b) as to a corporate officer, such personal responsibility would result from any acts of commission or omission which caused the adulteration of the food, including (but not limited to) gross negligence and inattention in discharging his corporate duties.

3. In a prosecution conducted on the theory that the accused might be convicted merely upon proof that he held a position of authority and responsibility in a corporation, did the introduction of evidence of an alleged prior offense, remote as to both time and place, require reversal since on the prosecutor's theory of the case there was no need for such evidence which would outweigh the prejudice resulting from its admission (although on retrial such evidence might be admissible)?

STATUTES INVOLVED

Section 301(k) of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1042, as amended, 21 U.S.C. 331(k), provides:

The following acts and the causing thereof are prohibited:

* * * * *

(k) The alteration, multilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

Sections 303(a) and (b) of the Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1043, as amended, 21 U.S.C. 333(a) and (b) provide:

(a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be

imprisoned for not more than three years or fined not more than $1,000, or both.

Section 402(a) of the Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1046, as amended, 21 U.S.C. 342 (a), provides in part:

> A food shall be deemed to be adulterated * * * (3) if it consists in whole or in part of any filthy, putrid, or decomposed susbtance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health * * *

STATEMENT

A. THE PROCEEDINGS IN THE DISTRICT COURT

This case arises from one of two similar prosecutions commenced in the District of Maryland following inspections of the Baltimore warehouses of two national retail food chains, both of which have their corporate headquarters in Philadelphia, Pennsylvania. Both cases were commenced within a year following the release of a report by the Comptroller General which recommended increased enforcement activity by the Food and Drug Administration ("FDA").[1]

In the first of the two District of Maryland cases, Food Fair, Inc., and a Food Fair vice president based in Towson, Maryland, were charged with violations of Section 301(k) of the Food, Drug and Cosmetic Act, *supra* at page 3, based on the presence of rodents in Food Fair's Baltimore warehouse. The charges against the individual corporate officer were subsequently dismissed at the request of the Government. Food Fair, Inc., pleaded guilty.[2]

[1] Comptroller General of the United States, Dimensions of Insanitary Conditions in the Food Manufacturing Industry, Report to the Congress, No. B-164031(2) (April 18, 1972).

In the second of the two cases, Acme Markets, Inc. ("Acme") and its president, John R. Park, respondent herein, were charged in a five-count information (A. 4-9) with violations of Section 301(k) of the Act, 21 U.S.C. § 331(k).

The alleged violations consisted of having caused five foods being held in Acme's Baltimore warehouse for sale after shipment in interstate commerce to become adulterated, principally "by reason of being rodent gnawed" (A. 9).

Acme is a national retail food chain employing approximately 36,000 persons with 874 retail outlets along the East and West Coasts, twelve main warehouses and four special warehouses (Pet. App. 5A). Park had his office in Acme's corporate headquarters in Philadelphia.

Acme's "Division 6" was headed by a divisional vice president Robert W. McCahan ("McCahan") with his office in Towson, Maryland, and consisted of a warehouse complex in Baltimore and approximately 110 retail outlets. The Baltimore warehouse was described in the trial testimony as a complex of approximately 250,000 square feet including an "older building" of three stories with a basement. An FDA inspection of this facility, which took twelve days in November and December 1971, discovered

[2] The circumstances concerning the prosecution of Food Fair and the dismissal by the Government of charges against the only individual named as a defendant in that case were developed in extensive post-verdict proceedings in the instant case, including affidavits and hearings held May 25, 1973, and July 5, 1973, on the issue of whether the Government's having named respondent Park as a defendant constituted an abuse of prosecutorial discretion. The trial court found that the instant case "comes as close to an abuse of that discretion as any one you would find" (Tr. of July 5, 1973, p. 32), but held that he must "reluctantly conclude that the motion must be denied . . . ." (Ibid, p. 33).

rodent infestation in the first floor and basement of the older building (A. 19-21). At the end of the inspection, the FDA issued to Edwin Zahn, the warehouse manager, a list of observations which described the rodent infestation (A. 20-23).

On January 27, 1972, the FDA sent a letter to Park, as president of Acme, with a copy sent to McCahan, described in the FDA letter as "Vice President in charge of the Baltimore Division" (A. 64-65). The FDA letter described the conditions found in the Baltimore warehouse and attached a copy of the list of observations previously given to the warehouse manager. McCahan responded to the letter on February 7, 1972 (A. 66-69), describing in detail the steps being taken to cure the deficiencies.

The Government's evidence established that "a great deal of effort" had been "made in the way of cleaning up the warehouse" (A. 23) following the 1971 inspection, and also "that there was still evidence of rodent activity" (A. 23) during a subsequent inspection in March 1972. At least one structural deficiency which might have contributed to the rodent activity found in the March 1972 inspection—a rusted door—was not discovered by the FDA until the second inspection (A. 26). A second letter was sent by the FDA to Park, again with a copy to McCahan. McCahan again responded to the letter, and, according to his testimony at trial, made an "all-out drive" to get in compliance (A. 37). McCahan testified that close to $70,000, including the cost of merchandise destroyed, new doors, rodent-proofing alterations, new automatic sweeping equipment, the hiring of ten additional people solely for cleaning duties, a supervisor for this new staff, and other efforts, was spent to cure the violations (A. 38).

An informal hearing pursuant to 21 U.S.C. § 335 was held in June 1972 at the Baltimore office of the FDA and attended by McCahan and other officers of Acme, not including Park.

In March 1973, the five-count information (A. 4-9) was filed in the United States District Court for the District of Maryland, charging both Acme and Park with violations of Section 301(k) of the Act, 21 U.S.C. § 331(k). The first four counts (A. 4-8) relate to violations discovered in the November and December 1972 inspection; the fifth count charges a violation found in the March 1972 inspection (A. 8-9).

Prior to trial, Park filed a motion seeking a bill of particulars as to Park's alleged liability for the violations (A. 10). The Government responded to the motion (A. 14) by disclosing that the evidence "will not show that the defendant personally performed the acts" described in the information but that the "Government's evidence will simply show that the defendant was a corporate officer who, under law, bore a relationship to the receipt and storage of food which would subject him to criminal liability under *United States* v. *Dotterweich*, 320 U.S. 277 (1943)" (A. 15).

Acme Markets, Inc. pleaded guilty to the five counts. At the trial of Park, the parties stipulated that the items of food described in the information had been shipped in interstate commerce and were being held for sale in the Baltimore warehouse (Tr. 34-38). An FDA investigator testified concerning evidence of rodent infestation and other insanitary conditions found in the Baltimore warehouse during the November and December inspection (A. 20-22), and concerning the results of the second inspection in March 1972:

> "Q. What did you observe in the course of your second inspection, sir? A. We found that there had been a great deal of effort made in the way of cleaning up the warehouse, reducing the total inventory and in rodent-proofing measures. We also found there was still evidence of rodent activity in the building and in the warehouses and we found some rodent-contaminated lots of food items" (A. 23).

The chief of compliance of FDA's Baltimore office testified concerning the correspondence with Park and McCahan (A. 30-34). The Government then called McCahan as a witness (A. 34-35). McCahan testified that the Baltimore warehouse was within the "geographical area" for which he was responsible and that he had prepared the letter responding to the first FDA letter to Park (A. 35). On cross-examination, McCahan testified concerning his efforts to "comply one hundred percent with the rules and regulations . . . ." (A. 38).

The Government's last witness was Acme's corporate assistant secretary who read a corporate by-law providing, in pertinent part, that the chief executive officer "shall, subject to the board of directors, have general and active supervision of the affairs, business, offices and employees of the company" (A. 40). The Government then introduced excerpts from Acme's Delaware corporate franchise tax records showing Park as president (Tr. 146-47).

At the conclusion of the Government's case in chief, the evidence concerning Park individually consisted, as the Government acknowledged to the court of appeals (Appellee's Brief, pp. 4-6) of the correspondence directed by the FDA to Park with copies to McCahan, and McCahan's response; the identification of Park as chief executive officer of Acme, and the text of Acme's by-law providing that the chief executive officer shall have "general and active supervision of the affairs, business, offices and employees of the company."

Respondent moved for a judgment of acquittal, which was denied by the trial court with the explanation that under *Dotterweich*, 320 U.S. 277, "the ultimate judgment should rest with the jury" (A. 42).

Park then testified on his own behalf concerning the care taken in sanitation matters, the technical competence of the persons concerned with sanitation (A. 44-46), and

the procedures followed in response to the FDA letter addressed to himself and McCahan (A. 46-47).

On cross-examination, Park testified that he was "responsible for the activities and affairs of the whole company" and that sanitation was "a thing that I am responsible for in the entire operation of the company" (A. 48-49). Over objection (A. 50-51), the Government introduced a letter (set forth at A. 70-71), concerning an alleged prior violation involving a rodent infestation in Acme's Philadelphia warehouse in March 1970 (A. 51-55).

The Government's requests for charge included a Requested Instruction No. 3 (A. 72) that "in order to find a defendant guilty on any count, you must find beyond a reasonable doubt for that count . . . As to the defendant, John R. Park, that he held a position of authority and responsibility in the operation of the business of Acme Markets, Inc." The charge as given used the Government's Requested Instruction No. 3 as the basis for the first two paragraphs dealing with Park's criminal liability. The substantive text of the charge (omitting the standard form instructions not at issue in the instant case) is as follows:

> "In order to find the Defendant guilty on any count of the Information, you must find beyond a reasonable doubt on each count, first, that the food that was held was held for sale in the Acme warehouse after shipment in interstate commerce.
>
> Secondly, that the food involved was held in unsanitary conditions in a warehouse with the result that it consisted, in part, of filth or where it may have been contaminated with filth.
>
> Thirdly, that John R. Park held a position of authority in the operation of the business of Acme Markets, Incorporated.

However, you need not concern yourselves with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets.

The corporation, Acme Markets, Incorporated, has already entered a plea of guilty to the charge placed against it, and, while that plea does not imply, in any way, the Defendant Park is guilty, the fact that the materials in question are foods held for resale after shipment in interstate commerce and held under unsanitary conditions are issues that are beyond question in the case and must be accepted by you.

The statute makes individuals, as well as corporations, liable for violations. An individual is liable if it is clear, beyond a reasonable doubt, that the elements of the adulteration of the food as to travel in interstate commerce are present. As I have instructed you in this case, they are, and that the individual had a responsible relation to the situation, even though he may not have participated personally.

The individual is or could be liable under the statute, even if he did not consciously do wrong. However, the fact that the Defendant is present and is a chief executive officer of the Acme Markets does not require a finding of guilt. Though, he need not have personally participated in the situation, he must have had a responsible relationship to the issue. The issue is, in this case, whether the Defendant, John R. Park, by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose" (A. 61-62).

Respondent objected to the instructions on the ground that they were not consistent with this Court's decision in *Dotterweich* (A. 62-63) and did not sufficiently define the standards applicable to Park's responsibility. After an extended colloquy, in which counsel referred to a discussion had previously in chambers concerning the instructions, the court stated:

> "Let me say this, simply as to the definition of the 'responsible relationship.' *Dotterweich* and subsequent cases have indicated this really is a jury question. It says it is not even subject to being defined by the Court. As I have indicated to counsel, I am quite candid in stating that I do not agree with the decision; therefore, I am going to stick by it" (A. 63).

The court cut off further discussion by stating to respondent's counsel "You have your objection " (A. 63). The jury returned a verdict of guilty on all counts.

Extensive post-verdict proceedings were had in which Park renewed his objections to the charge and the admission of evidence and also sought an acquittal on motions and affidavits alleging an abuse of prosecutorial discretion based on the Government's having prosecuted him solely because of his position as chief executive officer (see n. 2 at p. 5, *supra*). The trial court initially indicated a belief that an abuse of discretion requiring acquittal had been established (Tr. of May 25, 1973, p. 27), but subsequently concluded that the motion should be denied (n.2 at p. 5, *supra*). The court then imposed a fine of $50 on each of the five counts, substantially less than the one year's imprisonment or $1,000 fine, or both, provided for a first offense by 21 U.S.C. § 333(a), *supra* at p. 3, stating that by imposing this sentence he would "re-enforce" his previous "comments" on the merits of the prosecution's case (Tr. of July 5, 1973, p. 34).

B. THE DECISION OF THE COURT OF APPEALS

The court of appeals reversed the judgment of conviction and remanded the case for a new trial. The majority held that the charge did not correctly state the law as declared in *United States* v. *Dotterweich*, 320 U.S. 277. The court of appeals held that *Dotterweich* dispensed with the need to prove "awareness of wrongdoing" by Park but did not dispense with the need to prove that Park was "in some way personally responsible for the act constituting the crime" (Pet. App. 4A). The court concluded that since the statute prohibits "causing" the adulteration of food, the conduct required to be proved would be "acts of the accused which *cause* the adulteration of such food" (Pet. App. 4A). (Emphasis by the court of appeals.) The court enlarged upon this standard by stating that such "action" by respondent "may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' the contamination of the food" (Pet. App. 6A).

In response to the contention that the requirement of such proof would make enforcement more difficult, the court stated:

> "Nevertheless, the requirements of due process are intended to favor fairness and justice over ease of enforcement. We perceive nothing harsh about requiring proof of personal wrongdoing before sanctioning the imposition of criminal penalties" (Pet. App. 6A).

The court also held that the evidence of the alleged prior violation in Philadelphia in 1970, not charged in the information, should have been excluded as unduly prejudicial because, as the case was tried and submitted to the jury, "there was no actual need for the Philadelphia evidence" (Pet. App. 8A). The court expressly allowed the district court on retrial "to determine the admissibility of this 'prior crime' evidence in light of developments" (Pet. App. 9A).

SUMMARY

1. The court of appeals reversed the judgment of conviction because the instructions to the jury were contrary to this Court's interpretation of the Federal Food, Drug and Cosmetic Act of 1938 as declared in *United States* v. *Dotterweich*, 320 U.S. at 277. In the charge the jury was twice instructed that that "main" or "only" matter for their determination was whether the defendant John R. Park "held a position of authority and responsibility in the business of Acme Markets" (A. 61). Since respondent Park had been selected for prosecution because he was president and chief executive officer of Acme Markets, this portion of the charge was contrary to the fundamental principle that "a judge may not direct a verdict of guilty no matter how conclusive the evidence." *United Brotherhood of Carpenters* v. *United States*, 330 U.S. 395, 408.

The Government relies largely on the trial court's use of the phrase "responsible relation" and "responsible relationship," quoted from the *Dotterweich* decision; 320 U.S. 277, 281, 285, to sustain the remainder of the charge. But those phrases were not intended in *Dotterweich* to define for a jury the evidence necessary to a conviction; instead, *Dotterweich* refers to the "variety of conduct," 320 U.S. at 285, which would justify a conviction under "settled doctrines of criminal law . . . ." 320 U.S. at 284. In the instant case the trial Judge believed that the basis of Park's possible liability "was not even subject to being defined by the Court." (A. 63). The remainder of the charge reflected that belief and accordingly deprived the jury of the "appropriate guidance" which this Court intended in *Dotterweich*. 320 U.S. at 285.

2. The principles applicable to a retrial were correctly defined by the court of appeals. The statute as construed in *Dotterweich* dispenses with proof of "awareness of wrongdoing" by an individual defendant, but does not relieve the prosecution of the obligation to prove that an individual defendant has by acts of omission or commission directly or constructively caused the violations with which he is charged. As in any federal criminal prosecution, the Government has the burden to prove every element of the offense beyond a reasonable doubt. *Holland* v. *United States*, 348 U.S. 121, 138.

The language concerning "knowledge" contained in a subsequent decision by the same court of appeals, cited by the Government as proof that the court of appeals has now "in effect, repudiated the holding of *Dotterweich*," is actually language taken from the Government's own brief filed in that case.

The Government is correct that the statute as construed in *Dotterweich* does not impose a "vicarious" criminal liability on individuals for violations caused by others, and the reported cases confirm that in no case has an individual been convicted without proof of "the personal responsibility" which the court of appeals required be established on retrial in the instant case.

The broad range of proofs available to the Government on retrial, including "any of a host of other acts of commission or omission" which cause the violations (Pet. App. 6A), imposes no difficult or impractical burden. The guidelines used by the FDA and the Department of Justice have always (prior to the instant case) required exactly the same type of evidence before the commencement of criminal proceedings against individual corporate officers.

ARGUMENT

I. PREJUDICIAL ERRORS THROUGHOUT THE CHARGE REQUIRED REVERSAL OF PARK'S CONVICTION.

Reversible error was committed throughout the instructions, commencing with the error induced by the prosecutor, who persuaded the trial court to summarize the issue of respondent's personal criminal liability in language taken from the *dissenting* opinion of Mr. Justice Murphy in *Dotterweich*, 320 U.S. at 285-93.

The opening paragraph of the dissent in *Dotterweich* states the argument of the four-Justice minority against affirmance of the conviction. According to Mr. Justice Murphy:

> "There is no evidence in this case of any personal guilt on the part of the respondent. . . . Guilt is imputed to the respondent solely on the basis of his authority and responsibility as president and general manager of the corporation." 320 U.S. 285-86.

The Government's requested instruction No. 3 submitted to the trial court in the instant case (A. 72) not only sought to impute guilt to respondent Park "solely on the basis of his authority and responsibility as president" of Acme, but also directed the jury to find him guilty on that basis alone.

Instruction No. 3 was intended by the Government to summarize in four paragraphs the findings necessary to convict both Acme and Park. The first two paragraphs referred to factual proof of interstate shipments and the holding of goods under unsanitary conditions; the third paragraph referred to Acme's liability (and became irrelevant when Acme pleaded guilty); the text of the fourth paragraph, in its entirety, was as follows:

"4. As to the defendant, John R. Park, that he held a position of authority and responsibility in the operation of the business of Acme Markets, Inc."

The trial court charged the jury on the crucial issue of Park's liability in the exact words requested by the prosecutor. After defining the elements of interstate shipment and unsanitary conditions, the trial court stated:

"Thirdly, that John R. Park held a position of authority in the operation of the business of Acme Markets, Incorporated."

"However, you need not concern yourselves with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets." (A. 61)

This portion of the charge, combined with other portions also reflecting the view that criminal liability might be found without evidence of any "personal guilt" on the part of the respondent, as Mr. Justice Murphy contended was done in *Dotterweich*, caused the court of appeals to reverse (Pet. App. 3A). The court stated:

"The [trial] court charged the jury that the sole question was 'whether the Defendant held a position of authority and responsibility in the business of Acme Markets'; that Park could be found guilty 'even if he did not consciously do wrong' and even though he had not 'personally participated in the situation' if it were proved beyond a reasonable doubt that Park 'had a responsible relation to the situation.' We conclude that this charge does not correctly state the law of the case, that the conviction of Park on all counts must be reversed and a new trial awarded." (Pet. App. 3A)

A. The charge was contrary to the statute as construed by this Court in the Dotterweich decision.

The Government had contended in the district court and argued in the court of appeals "that the conviction may be predicated solely upon a showing that the defendant, Park, was the President of the offending corporation" (Pet. App. 4A; Appellee's Brief, pp. 4-6, 16-17). The instructions given to the jury were largely based on that theory.

The court of appeals rejected the Government's theory after analysis of the text of the statute as construed by the opinion of this Court in *Dotterweich*, 320 U.S. at 277. In a footnote to the opinion, the court of appeals also concluded that the trial transcript in the *Dotterweich* case did not support the Government's trial theory because the transcript showed "that Mr. Dotterweich personally made every executive decision and had direct personal supervisory responsibility over the physical acts which resulted in the interstate shipment of misbranded and adulterated drugs." (Pet. App. 3A-4A, n.3).[3]

[3] The Dotterweich prosecution was against both a corporation (Buffalo Pharmacal Company, Inc.) in business as a jobber of drugs and its president, Dotterweich. The printed Record filed in this Court shows not only that Dotterweich was personally responsible for every aspect of the corporate defendant's business but also that he testified at trial in a manner which emphasized that personal responsibility.

The violations charged in the case arose from two shipments of digitalis alleged to be less potent than required by law and a shipment of pills alleged to be misbranded because the contents, although correctly stated on a label, did not conform with the National Formulary definition. Both the corporation and Dotterweich vigorously defended on the merits of every issue, claiming that the digitalis was of proper potency, attacking the Government's tests, and contending that the pills were properly labeled. Except for expert witnesses, the defendants' testimony was presented by Dotterweich himself, who was called and recalled on four separate occasions in a two-day trial (Record 125, 140, 156, 159). The evidence showed that the corporate defendant had been "created" by Dotterweich, in the words of defense counsel (R. 63), was owned by him, had approximately 26 employees, working on one floor of an office building, with Dotterweich

The issue presented to this Court in *Dotterweich* was whether an individual employed by a corporation could *ever* be held liable under the Act, since the court of appeals had held, 131 F.2d 500, that the structure of the guaranty provisions of the Act manifested a congressional intent to exclude such liability unless the corporation was operated as the "alter ego" of the individual.

The opinion of the Court by Mr. Justice Frankfurter noted that the penalty provisions of the statute reach "any person" who violates its substantive provisions, and that the word "person" was defined to include a corporation. 320 U.S. at 281. The opinion then states:

> "But the only way in which a corporation can act is through the individuals who act on its behalf. *New York Central & H.R.R. Co.* v. *United States,* 212 U.S. 481. And the historic conception of a 'misdemeanor' makes all those responsible for it equally guilty, *United States* v. *Mills,* 7 Pet. 138, 141, a doctrine given general application in § 332 of the Penal Code (18 U.S.C. § 550)."

Note 3—Continued

as president and "General Manager." Dotterweich was the only supervisor when he was present (R. 18) and "he was there most every day all day" (R. 17). During the testimony by Dotterweich, his counsel almost invariably used the word "you" to refer to actions taken in respect of the challenged shipments even when referring to actions taken by other employees who worked under Dotterweich's supervision, such as "I show you the original order that *you* sent" (R. 128); "did *you* buy any digitalis tablets from any other concern?" (R. 141); and "Mr. Dotterweich, did *you* continue to so sell digitalis tablets from that batch after that?" (R. 142) (emphasis added). On cross-examination, Dotterweich admitted that "When I am in the place, I am in charge," that he was "the boss," and that he must have been in charge on a day when one of the challenged shipments went out (R. 143-44).

The jury in the *Dotterweich* case found the individual defendant Dotterweich guilty on all counts but disagreed as to the guilt of the corporation. The verdict is explainable by the extent to which the defendants' evidence had been identified with Dotterweich personally, particularly by use of the words "I," "my," "his," and "you," while the corporate defendant was infrequently referred to except in the formal identification of documents and other exhibits.

Section 332 of the former Penal Code, then codified as § 550 of Title 18, is now codified as 18 U.S.C. § 2 and states the general rule, applicable to all federal crimes, concerning those who aid and abet the commission of an offense:

> "§ 2. Principals
>
> (a) Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission is punishable as a principal.
>
> (b) Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal." As most recently amended, 65 Stat. 717.

The opinion then considered the basis of the holding by the court below concerning the guaranty provisions of the Act, now codified as 21 U.S.C. § 333(c), and held that "the want of a guaranty does not cut down the scope of responsibility of all who are concerned with transactions forbidden by § 301". The following sentence of the opinion comments on the effect of this holding:

> "To be sure, that casts the risk that there is no guaranty upon all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor." 320 U.S. at 284.

Particularly important is the reference to "settled doctrines of criminal law" concerning those who "are responsible for the commission of a misdemeanor." This language refers back to the citation, 320 U.S. at 281, of *United States* v. *Mills,* 7 Pet. at 141, which holds that all those responsible for a misdemeanor may be prosecuted as principals, and is the historic origin of the doctrine given general application in the statutory language now codified as 18 U.S.C. § 2.

Of equal importance is the language in which this Court refutes the view that a limiting construction of the Act might be necessary because otherwise the statute would "operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment." The opinion then states:

> "But that is not the way to read legislation. Literalism and evisceration are equally to be avoided. To speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty." 320 U.S. at 284.

The last sentence, introduced with the words "to speak with technical accuracy" written by a Justice who had an unusual respect for the technical side of the law, is of critical importance as applied to the instant case. When this language is read in context with the earlier citation to former 18 U.S.C. § 550 and "'settled doctrines of the criminal law," the meaning is plain that this Court did not intend to apply to Federal Food and Drug Act violations a special standard in which the jury would enjoy the untrammeled discretion claimed by the Government in the instant case.

The next sentence of the *Dotterweich* opinion further confirms that conclusion.

> "Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance." 320 U.S. at 284.

The concluding sentences of the opinion, quoting the comment by trial counsel for Dotterweich that the trial court in that case had delivered "a very fair charge," 230 U.S. at 285, should not be read to validate the charge as

given in *Dotterweich* as a pattern or formula is applicable to all prosecutions of a corporate officer, regardless of the factual issues which are presented by the evidence. As previously noted (n.3 at p. 17, *supra*), there was no significant effort made at that trial to establish a lack of personal liability by the individual defendant if the defenses (which sought to establish a complete absence of liability on the part of both defendants) were not accepted by the jury. Moreover, the correctness of the charge was never at issue in any stage of the *Dotterweich* case, since counsel had raised no objection at trial and no effort was made to argue the correctness of the charge either in the court of appeals or in this Court. Even so, the charge concerning Dotterweich's liability, including the key sentence "was he responsible for the shipment of them in interstate commerce?" (quoted at page 24 n.11 of Brief for the United States) offered considerably more guidance to the jury than was given in the instant case.

B. The crucial portion of the charge erroneously directed a verdict of guilty based solely on Park's status as chief executive officer of the corporation.

A fundamental principle of criminal procedure is that "a judge may not direct a verdict of guilty no matter how conclusive the evidence." *United Brotherhood of Carpenters* v. *United States,* 330 U.S. 395, 408.

The instruction in the instant case that the "main issue" for the jury was "only with the third element, whether the defendant held a position of authority and responsibility in the business of Acme Markets" (A. 61), was in every significant sense a directed verdict of guilty. Park was selected as the recipient of the FDA letters and as the defendant to be named individually in the case because of his "position of authority and responsibility in the business of Acme Markets." The instruction therefore used the basis of the Government's selection of Park as the foundation for a direction to find Park guilty.

The error in this crucial portion of the charge requires reversal, even more than did the single error in "36 separate instructions to the jury, which covered some 52 pages of the transcript" in *Cool* v. *United States,* 409 U.S. 100, 106. (Dissenting opinion of Rehnquist, J.).

Even "an equivocal direction to the jury on a basic issue" requires reversal. *Bollenbach* v. *United States,* 326 U.S. 607, 613. The rule that "a conviction ought not to rest on an equivocal direction to the jury on a basic issue," as declared in the *Bollenbach* decision, is equally applicable to convictions under regulatory statutes. *M. Kraus & Bros., Inc.* v. *United States,* 327 U.S. 614, 626-27. (Emergency Price Control Act.)

"Nor is it enough for [this Court] to conclude that guilt may be deduced from the whole record." *Bihn* v. *United States,* 328 U.S. 633, 637. The Court is "not authorized to look at the printed record, resolve conflicting evidence, and reach the conclusion that the error was harmless because we think the defendant was guilty." *Weiler* v. *United States,* 323 U.S. 606, 611.

C. The remainder of the charge failed to provide "appropriate guidance" or any other meaningful standard for the jury.

The Government's brief on the merits does not argue the correctness of much of the charge given in the instant case. To the extent that the Government attempts to justify the charge, reliance is placed largely on the trial court's use of the phrase "responsible relation" or "responsible relationship."

In using those phrases, taken from the *Dotterweich* opinion, the trial court acted on the belief that no better definition than "responsible relationship" could be formulated because:

> "*Dotterweich* and subsequent cases have indicated this really is a jury question. It says it is not even subject to being defined by the Court." (A. 63).

This belief led the trial court into the error warned against in the recent edition of Devitt & Blackmar, *Federal Jury Practice and Instructions,* § 8.02, pp. 172-73 (1970):

> "Sometimes counsel will quote verbatim from an appellate court decision dwelling on a point involved in the trial, and urge it as a proposed instruction. Appellate court opinions are written for a purpose different from that for which jury instructions are designed. The point of law may be controlling, but not the language. It is the legal principle, not the words expressing it, which is pertinent and which will be helpful to the jury. Legal points from decided cases should be couched in language appropriate to the facts and to the parties in the lawsuit."

As used in the instant charge, the phrases "responsible relation" and "responsible relationship" were so ambiguous as to leave the jury without any standard whatsoever to determine Park's criminal liability, as defendant's trial counsel vigorously contended (A. 64-65). The Government supports the charge largely on the basis of those phrases, citing the *Dotterweich* opinion. (See Brief for the United States, pp. 22-23).

Even if the phrase "responsible relation" had been intended by this Court as the rule of liability for violations, that phrase alone, without explanation or definition, would not provide the operative words of a charge, for the reasons stated in the excerpt from Devitt & Blackmar quoted above. Moreover, the phrase "responsible relation" was not used in the *Dotterweich opinion,* 320 U.S. at 281, 285, to define the conduct which would constitute a violation of the statute. The phrase is used instead to describe those persons "standing in responsible relation to a public danger" on whom duties are imposed. 320 U.S. at 281,

citing *United States* v. *Balint*, 258 U.S. 250. The second reference to "responsible relation" again refers to "the class of employees which stands in such a responsible relation." 320 U.S. at 285. Since Dotterweich was a person "standing in responsible relation to a public danger," 320 U.S. at 281, by reason of his position as general manager of a drug jobber, there was a "variety of conduct" for which he might be found criminally liable. 320 U.S. at 285. Nor does the *Dotterweich* decision demand that every case commenced by the Government after referral from the FDA be sent to the jury, contrary to the belief of the trial Court in the instant case, who stated his reading of the decision that "the ultimate judgment should rest with the jury" (A. 42) in denying the motion for acquittal at the close of the Government's evidence.

The *Dotterweich* decision holds that liability "depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance." 320 U.S. at 284. The absence of such guidance in the instant trial, combined with the erroneous instruction directing a verdict of guilty if Park "held a position of authority and responsibility in the business of Acme Markets" (A. 61), requires reversal and a new trial.

II. THE COURT OF APPEALS CORRECTLY STATED THE PRINCIPLES APPLICABLE TO A RETRIAL.

A. Conviction under the statute as construed in Dotterweich requires proof of causation consisting of acts of omission or commission which directly or constructively cause the violations with which the defendant is charged.

The court of appeals held that the statute as construed in *Dotterweich* dispensed with the need to prove "awareness of wrongdoing" but did not dispense with the

need to prove "wrongful action" by Park. (Pet. App. 4A). The court reached this conclusion because:

> "As a general proposition, some act of commission or omission is an essential element of every crime. For an accused individual to be convicted it must be proved that he was in some way personally responsible for the act constituting the crime. The Supreme Court recognized this in *Dotterweich:* 'The offense is committed * * * by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws * * *' 320 U.S. at 284."

Unless the statute creates a true "vicarious" liability, by which an individual corporate officer may be criminally liable without "any personal guilt," the court of appeals was correct to require proof of some act of commission or omission. The Government now disclaims any "vicarious" liability for individual corporate officers (Brief, p. 14; see the discussion *infra* at p. 30).

The court noted that the relevant section of the statute prohibits "causing" the adulteration of food (Pet. App. 4A n.4) and accordingly defined "'wrongful action' in this context as acts of the accused which *cause* the adulteration of such food" *(Ibid.)*. The court went on to hold that such acts as to Park "may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' the contamination of the food" (Pet. App. 6A) (footnotes omitted).

The Government's argument against this holding is lengthy but difficult to define. At several points, the Government contends that the court has required "affirmative 'wrongful action' by the accused" (Brief, p. 24) or that the court erred "in requiring affirmative 'wrongful action' by a corporate official . . . ." (Brief, p. 15). But these shorthand

expressions misread the court of appeals decision since the court clearly held that acts of omission might be the basis for individual criminal liability and that acts of omission might be used to show participation either "directly or constructively" in the violations (Pet. App. 5A).

If the Government intends the words "affirmative 'wrongful action'" to refer to the Government's obligation to prove acts by the accused which cause the adulteration of the food "directly or constructively" (Pet. App. 5A), then the objection to proof of those acts should also fail. The Government made the same argument in the court of appeals that a requirement of such proof might make enforcement more difficult. The court of appeals stated:

> "Nevertheless, the requirements of due process are intended to favor fairness and justice over ease of enforcement" (Pet. App. 6A).

This Court has held that "proof of a criminal charge beyond a reasonable doubt is constitutionally required." *In Re Winship,* 397 U.S. 358, 362. In any federal criminal prosecution "the Government must still prove every element of the offense beyond a reasonable doubt though not to a mathematical certainty." *Holland* v. *United States,* 348 U.S. 121, 138 ("net worth" method of proof of violation of Internal Revenue Code). The court of appeals correctly applied these principles to the instant prosecution, while carefully excluding the necessity, pursuant to the statute as construed in *Dotterweich,* that the Government prove "awareness of wrongdoing."

There is no possible justification now to change the Constitutional standard of proof applicable to all federal criminal prosecutions so as to relieve the Government from proving some act of omission or commission by Park which "directly or constructively" caused the violations.

B. The holding in the Abbott Laboratories decision concerning "knowledge" is a holding sought by the Government in order to justify certain grand jury inquiries held to be immaterial and prejudicial by a trial court.

The Government charges that the court of appeals has recently "compounded" its alleged error in the instant case by having "in effect, repudiated the holding of *Dotterweich*" in a recent decision, *United States* v. *Abbott Laboratories,* No. 74-1230 (4th Cir. Oct. 2, 1974), petition for a writ of certiorari pending, No. 74-699. The Government's brief states:

> "The error of the court below in requiring proof of 'wrongful action' by the defendant is compounded by that court's subsequent decision in *United States* v. *Abbott Laboratories, supra.* In its decision in the present case, the court at least purported to recognize that the 1938 Act 'dispenses with • • • awareness of some wrongdoing' (Pet. App. 4A). In *Abbott Laboratories,* however, the court held that 'responsibility' under the Act 'depends upon knowledge, and • • • on the action or nonaction of the officer or employee after he has obtained knowledge' (slip op., p. 20). In this more recent explication of its view of the 1938 Act, the court of appeals has, in effect, repudiated the holding of *Dotterweich, supra.*" (Brief, p. 25)

The truth is that the holding of the court below in the *Abbott Laboratories* case, and which holding the Government advances as an argument for reversal in the instant case, is a holding sought by the Government and rendered in language substantially similar to that which appears in the Government's brief filed in the *Abbott Laboratories* case.[4]

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[4] Two Government counsel shown on the brief filed in *Abbott Laboratories* are also shown on the brief filed in this Court in the instant case, but presumably neither was involved in the preparation of both briefs.

In the *Abbott Laboratories* prosecution, the Government had obtained indictments against Abbott Laboratories and five individuals charging violations of the statute resulting from shipments of allegedly adulterated intravenous solutions. The release of the indictments was accompanied by widespread publicity concerning deaths allegedly caused by shipments of the intravenous solution, some of which publicity was alleged by the defendants to have originated with the FDA and the Government prosecutors.

The defendants also alleged that the prosecution was guilty of misconduct before the grand jury, including an examination of one of the defendants (Robert O'Donnell) in which O'Donnell was cross-examined concerning newspaper articles which referred to deaths allegedly caused by the intravenous solution. One of the defense contentions was that the deaths were "in no way involved in the case" but that "the prosecutors repeatedly flaunted the stories of deaths before the grand jury," justifying dismissal of the indictments" (Pet. App. C2, opinion of the district court).

The district court agreed with this contention as one of several grounds on which to quash the indictments:

> "To raise the spector of homicide before the grand jury in an effort to obtain an indictment under an act which requires no *mens rea* is unconscionable conduct" (Pet. App. C18).

The Government then sought in the court of appeals to reverse this holding by establishing a proper basis for having cross-examined O'Donnell concerning the alleged deaths. The Government's brief filed in the *Abbott Laboratories* appeal argues as follows:

> "The offense under Section 301(a) is committed, except under circumstances not here relevant, by all who share in responsibility in the business process of distributing in interstate commerce the adulterated or misbranded drugs. *Dotterweich, supra,* 320 U.S. at 284. Thus, the responsibility of individuals within the Abbott organization for distribution of misbranded products would turn upon their relationship in the corporation to production and distribution activities, and any knowledge they may have with respect to problems arising from use of the drug. For example, an official not normally connected with such activities who was sent to investigate reports of deaths and illnesses of various hospitals might become responsible by reason of his knowledge. The references to deaths, including the questioning of Mr. O'Donnell as to his reactions and those of others upon receiving notice of illnesses and deaths, were therefore within the proper scope of investigation, not unduly prejudicial and not grounds for dismissal of the indictment." (Brief for the United States, p. 29)

The court of appeals agreed with this argument and reversed the district court, stating:

> "Defendants were indicted under 21 U.S.C. § 331(a), which prohibits the introduction of any drug 'that is adulterated or misbranded.' While § 331(a) prescribes a crime of which scienter is not a necessary element, it does not follow that, in addition to Abbott, every employee of Abbott would have potential criminal liability; rather, only those who share in the responsibility of distributing adulterated or misbranded drugs in interstate commerce are potentially criminally liable. *United States* v. *Dotterweich,* 320 U.S. 277, 281, 284 (1943); *United States* v. *Park,* ____ F.2d ____ (4 Cir., June 28, 1974). 'Responsibility' in turn depends upon knowledge, and if knowledge is established it depends further on the action or nonaction

of the officer or employee after he has obtained knowledge. Thus, we think that an inquiry to Mr. O'Donnell of whether he had knowledge from various sources of the charge that Abbott solutions caused deaths, as a prelude to the ultimate inquiry of what action he took with respect thereto, was relevant to the proceedings." (Pet. App. A13-A14).

Comparison of the opinion with the language used in the Government's brief shows that the court of appeals accepted both the argument and the language used by the Government.

Moreover, the argument made by the Government in the *Abbott Laboratories* brief appears to some degree inconsistent with the argument made in the instant case that the Government should be relieved from investigating the nature of Park's relationship to the alleged violations and relieved from proving the acts of commission or omission by Park which directly or constructively caused those violations. Under the Government's own guidelines, as discussed *infra* at p. 33, the FDA and the Department of Justice have never commenced prosecutions against individual corporate officers without first gathering exactly that type of evidence, as the Government was engaged in gathering in the *Abbott Laboratories* investigation.

C. The Government is correct that criminal liability of an individual charged under the statute is never a vicarious liability for the conduct of others.

The Government correctly states that the criminal liability created as to corporate officers by the statute "is not vicarious" (Brief, p. 14), by which respondent understands the Government to mean that a conviction should depend on the conduct of the corporate officer concerning the alleged violations. Conversely, a conviction of one individual should not, on the Goverment's view, depend solely upon the personal guilt of other individuals.

The reported cases support the conclusion that liability under the statute is not vicarious, and show that the FDA has rarely, if ever, established individual criminal liability in cases which did not involve facts showing "the personal responsibility" which the court of appeals required be established on retrial in the instant case. The reported decisions now relied on in the Government's brief (pp. 25-26) all involved such facts as to the individuals named as defendants.

In *H. B. Gregory Co.* v. *United States,* 502 F.2d 700 (7th Cir.), decided March 14, 1974, pending on petition for a writ of certiorari, No. 74-142, the facts established that the individual defendant "was in charge of the sanitation program and specifically the rodent control program in the warehouse; and that he was there on a daily basis" (Appendix 1 to the petition, opinion of the court of appeals, pp. 5-6). In *United States* v. *Shapiro,* 491 F.2d 335 (6th Cir. 1974), the individual defendant had *pleaded guilty* and received a "probated two-year sentence" conditioned upon compliance in the future with the Act. The holding of the court of appeals that the defendant could not avoid revocation of his probation by pleading the defense that the business was subject to agreement of sale at the time of the violations is entirely consistent with the holding of the court of appeals in the instant case. *United States* v. *Cassaro, Inc.,* 443 F.2d 153 (1st Cir. 1971), involved evidence (appearing from the opinion to have been uncontested) that the individual defendant ordinarily was present at the bakery in which the violations were found and was personally in charge of its operations. 443 F.2d at 154, 157. The individual defendant's only contention on appeal was that he had been temporarily "out sick" at the time of the inspection. In *Lelles* v. *United States,* 241 F.2d 21 (9th Cir. 1957), *cert. denied,* 353 U.S. 974, the individual defendant was charged with having "personally" caused the offenses, 241 F.2d

at 24, and was convicted even though the corporate defendant was ordered acquitted. *United States* v. *Kaadt,* 171 F.2d 600 (7th Cir. 1948), is a case similar to *Dotterweich* in which the individual defendants took responsibility for distributing a drug, with printed matter signed by one of the individual defendants, but contended that no violation whatsoever had been committed by anyone, corporation or individual. *United States* v. *Parfait Powder Puff Co.,* 163 F.2d 1008 (7th Cir. 1947), *cert. denied,* 332 U.S. 851, does not involve individual criminal liability. In *United States* v. *Diamond State Poultry Co.,* 125 F. Supp. 617 (D. Del. 1954), the two individual defendants were so much a part of the activities from which the violations arose that the court expressly found for the purpose of sentence that there was "an identity between individual and corporate defendants. . . . " 125 F. Supp. at 620.

In none of these cases did the Government attempt to establish individual criminal liability without proof of acts of the accused which caused the violations.[5]

D. No impractical burden is imposed by requiring proof of acts of omission or commission which cause the offenses charged, because the Government has always previously required evidence of such acts as a condition precedent to prosecution of individual corporate officers.

[5] Commentators have sometimes reached the contrary conclusion that the statute does create a "vicarious" liability, either on the basis of the dissent in *Dotterweich* or because they have used a different definition of "vicarious." One example of the latter is the article by D. F. O'Keefe, Jr. and M. H. Shapiro, "Personal Liability Under the Federal Food, Drug, and Cosmetic Act—The *Dotterweich* Doctrine," 30 Food Drug Cosmetic Law Journal 3 (Jan. 1975), in which the authors state the opinion that "*close and immediate supervisory control by the defendant over the operation in which the violative act occurred has always been present when individuals have been held vicariously liable.*" (Ibid., p. 20) (Emphasis in the original). Evidence of that sort is exactly the evidence described by the court of appeals in the instant case as "evidence of personal guilt."

The FDA's own standards for selection of individuals to prosecute for violations of the statute, as summarized in the Government's brief (pp. 31-32), already include a determination whether some act of omission by a corporate officer has caused a violation. The Government plainly believes that numerous acts of omission by Park caused the Baltimore warehouse violations and spells out in a lengthy footnote (Brief, p. 34 n.19) the factual details of a long series of such alleged omissions. Accordingly, no improper burden will be placed upon the Government by requiring proof at trial of acts of omission or commission constituting causation.[6]

III. EVIDENCE OF ALLEGED PRIOR CRIMES SHOULD HAVE BEEN EXCLUDED AT THE FIRST TRIAL AND WILL BE ADMISSIBLE AT A SUBSEQUENT TRIAL ONLY IF THE NEED FOR SUCH EVIDENCE OUTWEIGHS ITS PREJUDICIAL EFFECT.

The court of appeals held that on retrial evidence of prior violations during 1970 in Acme's Philadelphia warehouse might properly be admitted, depending on "the prosecution's new approach to the presentation of its case" (Pet. App. 9A).

The decision of the court below that the evidence of the 1970 violation should not have been admitted at the first trial was based largely upon the prosecution's trial theory, reflected in the charge, that Park should be convicted if he held "a position of authority and responsi-

[6] An "impractical burden" might be imposed if the Government were required to prove that an officer "knowingly or willfully . . . caused the specific violations" (Brief for the United States, p. 38), but no such requirement is imposed by the court of appeals decision. Nor does that decision require proof that an officer or warehouse manager had knowledge "that a particular lot of food was contaminated" (*Ibid.,* p. 38). These references to "knowledge" perhaps refer to the language in the *Abbott Laboratories* decision, which is discussed *supra* at pp. 27-30, and in which the court of appeals accepted the argument urged by the Government.

bility in the business of Acme Markets" (Pet. App. 8A). In a prosecution conducted on this theory, "in light of the sole issue presented, *need* for the Philadelphia evidence is not apparent" (Pet. App. 8A; emphasis by the court of appeals).

The rule applied by this Court and by the court below is that evidence of other criminal offenses by the defendant, not charged in the indictment or information, is not admissible for any purpose, *Boyd* v. *United States,* 142 U.S. 450, 458; *Lovely* v. *United States,* 169 F.2d 386, 389 (4th Cir. 1948), *cert. denied,* 338 U.S. 834, subject only to a balancing test where need for such evidence outweighs the prejudice which is created by its admission. *United States* v. *Woods,* 484 F.2d 127 (4th Cir. 1973).

During the trial of Park, the prosecution left no doubt in the minds of the jury that the alleged violations described in the FDA letter concerning the 1970 inspection of Acme's Philadelphia warehouse (A. 70) were considered by the Government to constitute "prior crimes" within the meaning of the rule which ordinarily excludes such evidence. In one episode which took place at the close of Park's testimony, which was also the close of all the evidence, Park was examined by his counsel concerning the alleged 1970 Philadelphia violations. Park testified that no one from the FDA had expressed dissatisfaction concerning Acme's handling of the 1970 matter (A. 56). The prosecutor, on recross examination, then asked the question (to which an objection was immediately made and sustained): "Well, you do stand before the jury as a criminal Defendant today, don't you?" (A. 57). This comment was followed by a summation in which the prosecutor referred to the alleged 1970 violations interchangeably with those charged in the information (A. 58-60).

On retrial, both the Government's trial theory and greater restraint in the use of evidence of prior violations may justify admission if the need outweighs the prejudicial effect.

CONCLUSION

For the reasons stated, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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In the Supreme Court of the United States

OCTOBER TERM, 1974

UNITED STATES OF AMERICA, PETITIONER

v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

REPLY BRIEF FOR THE UNITED STATES

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1. The Federal Food, Drug and Cosmetic Act does not create a "status" offense.

1. Respondent Park and the amici contend that the government seeks to base Park's criminal responsibility "solely on Park's status as chief executive officer of the corporation."[1] Some of the amici characterize this asserted theory as the imposition of "vicarious liability"[2] and another ar-

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[1]Park Br., p. 21; see Synthetic Organic Chemical Manufacturers Association ("SOCMA") Br., p. 15; National Canners Association ("Canners") Br., pp. 21-22; National Association of Food Chains ("Food Chains") Br., pp. 13, 16; Grocery Manufacturers of America ("GMA") Br., pp. 4, 17.

[2]SOCMA Br., pp. 8, 15; Food Chains Br., pp. 9, 13 n. 2, 16; GMA Br., p. 3.

gues that this alleged approach improperly dispenses with "*actus rea*" or "causation."[3]

These generalized claims fail to recognize the unique character and special importance of the pure food and drug laws. This Court has long recognized that "the public interest in the purity of its food [and drugs] is so great as to warrant the imposition of the highest standard of care on distributors—in fact an absolute standard which will not hear the distributor's plea as to the amount of care he has used." *Smith* v. *California*, 361 U.S. 147, 152. "In the interest of the larger good [the Food, Drug and Cosmetic Act of 1938] puts the burden of acting at hazard upon a person otherwise innocent but standing in a responsible relation to a public danger." *United States* v. *Dotterweich*, 320 U.S. 277, 281. The 1938 Act thus imposes an affirmative duty on those "standing in a responsible relation to a public danger": it requires them to seek out and to prevent insanitary conditions. In this manner "the distributors of food [are made] the strictest censors of their merchandise * * *." *Smith* v. *California, supra*, 361 U.S. at 152.

Once this duty to exercise "the highest standard of care"—which Park and the amici do not discuss—is recognized, it is evident that the 1938 Act does not punish "status" or impose "vicarious liability." The corporate officer in a "responsible relation to a public danger" has a *personal* affirmative duty to become informed about, and a duty to act to prevent, conditions that violate the Act. In making him criminally responsible for his failure to discharge that duty, the law punishes his *own* failure to act; it does not make him "vicariously" liable for the act of another. It punishes "neglect where the law requires care, or inaction where it imposes a duty." *Morissette* v. *United States*, 342 U.S. 246, 255.

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[3]Canners Br., pp. 16, 21.

Similarly the element of "causation" urged by Park (Br., p. 24) and Canners (Br., p. 21) inheres in the failure of the responsible corporate official to seek out and prevent insanitary conditions that could have been prevented. The legislative history of the 1938 Act—our view of which has not been seriously disputed—shows that the 1938 Act punishes acts of omission as well as willful violations. See United States Br., pp. 27-28. Thus the Senate report on S. 2800 spoke of the penalties reserved for "those who violate the law through inadvertence, carelessness, or negligence" (S. Rep. No. 493, 73d Cong., 2d Sess., p. 20).[4]

The 1938 Act does not create "status" offenses. "Status" offenses improperly permit the imposition of criminal penalties "upon a person for being in a condition he is powerless to change." *Powell* v. *Texas*, 392 U.S. 514, 567 (Fortas, J., dissenting). In contrast, the criminal liabilities created by the 1938 Act rest squarely upon a corporate official's *power* to affect the prohibited condition. Responsible corporate officials "have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce." *United States* v. *Dotterweich, supra*, 320 U.S. at 285. Moreover, a claim by the official that he is

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[4]While Park and some of the amici acknowledge the possibility of liability based on failures to act, they suggest a standard of gross negligence (Park Br., pp. 25-26; Food Chains Br., pp. 13-15; GMA Br., p. 11). Yet in 1948 Congress refused to adopt an amendment to Section 303(a), passed by the Senate, which would have imposed criminal liability only for violations committed "willfully or as a result of gross negligence " (see United States Br., pp. 29-30.)

"powerless" may "be raised defensively at a trial on the merits." *United States* v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91.[5]

2. The charge did not require the jury to find Park guilty solely on the basis of his status.

Park (Br., p. 21), by isolating one sentence in the jury instructions, argues that the entire charge amounts to a direction of a verdict based on his status as chief executive officer of Acme. However, "a single instruction to a jury may not be judged in artificial isolation, but must be viewed in the context of the overall charge." *Cupp* v. *Naughten*, 414 U.S. 141, 146-147; *Boyd* v. *United States*, 271 U.S. 104, 107.

When the charge is viewed as a whole, it is clear that the jury was not directed to find Park guilty solely on the basis of his status as chief executive. To the contrary, the trial judge specifically admonished the jury that, "the fact that the Defendant is [president] and is a chief executive officer of the Acme Markets does not require a finding of guilt." Moreover, the jury was specifically asked to determine whether "the individual had a responsible relation to the situation," and, later, whether he "had a responsible relationship to the issue [which] * * * is, in this case, whether the Defendant * * * had a position of authority and responsibility in the situation out of which these charges arose." (For complete instruction, see United States Br., pp. 10-11.) A reading of the entire instruction indicates that the jury was specifically advised to consider

[5]A "status" offense may also involve "punishment for a mere propensity, a desire to commit an offense; the mental element is not simply one part of the crime but may constitute all of it." *Powell* v. *Texas, supra*, 392 U.S. at 543 (opinion of Black, J.). Obviously the criminal liability created by the 1938 Act for discrete instances of food contamination punishes neither a "propensity" nor a "condition" of the responsible corporate official.

Park's relationship to the insanitary conditions that formed the basis of the information.

3. The charge was consistent with this Court's holding in Dotterweich.

In an attempt to narrow the effect of this Court's ruling in *Dotterweich*, Park states (Br., p. 21) that no significant effort was made by Dotterweich at trial to establish a lack of personal liability. The record in *Dotterweich* does not support this assertion. Dotterweich, like Park, made every attempt to deny his personal involvement in the violative shipments. He testified, *inter alia*, that "[t]he company is almost automatic in its operation" and that, as a result of health problems, "I do so little now that I leave Mr. Munn in charge." Munn testified that he (and not Dotterweich) had "taken complete charge of the receiving and shipping end" of the business, that he created the system for shipping drugs and that he (and not Dotterweich) supervised the shipments in question.[6] In fact, Munn testified that some "third person" could have made the violative shipment (Record on Appeal, No. 5, O.T. 1943, pp. 29, 30-32, 35, 129, 143 and 144; see also United States Br., p. 19, n. 8).

Park also states (Br., p. 18) that the issue before this Court in *Dotterweich* was whether an individual employed by a corporation could "ever" be liable under the Act. But Dotterweich repeatedly and continuously argued to this Court that there "had to be some act * * *," and that a second trial was necessary to fully explore "the question of fact as to whether [he] had any connection with [the] shipment" (see Memorandum in Opposition to Petition for a Writ of Certiorari, No. 5, O.T. 1943, p. 5-6; Brief for

[6]Compare Park's testimony, at A. 55, to the effect that while he is ultimately responsible for the entire operation of the company, he "would hold Mr. McCahan responsible" for any failure in Baltimore.

Respondent, No. 5, O.T. 1943, p. 5 and Point Two, "The respondent was the agent of the defendant corporation and some wrongful act on his part must be shown," p. 15; and Petition for Rehearing, No. 5, O.T. 1943, p. 6).

In short, the arguments advanced by Park today were squarely before this Court more than thirty years ago. Park, like Dotterweich, is guilty not solely because of his title, but because he had the duty, the power and the authority to discover and prevent the violation in the first instance, and because he failed to do so.

4. Responsibility under the 1938 Act does not depend on knowledge.

Park argues (Br., pp. 27-32) that the statement of the court of appeals in *United States* v. *Abbott Laboratories*, 505 F. 2d 565, 573, to the effect that " '[r]esponsibility' * * * [under the 1938 Act] depends upon knowledge * * * ," merely reiterated the government's argument on appeal in that case. In *Abbott Laboratories*, a prosecution under the 1938 Act for distributing misbranded and adulterated drugs, the district court had dismissed the indictment because it found that the prosecutor had prejudiced the grand jury by inquiring of grand jury witnesses whether they were aware of reports of deaths resulting from contaminated intravenous solutions made by Abbott Laboratories. 369 F. Supp. 1396, 1405 (E.D.N.C.).

In reversing the district court's dismissal of the indictment, the court of appeals stated that the evidence in question was relevant to establish criminal responsibility under the Act because " '[r]esponsibility' * * * depends upon knowledge * * *." However, contrary to Park's assertion (Br., pp. 27-30), the government did not argue that an individual's criminal responsibility under the Act depends upon his knowledge of a violation of the Act.

Rather, the government argued that evidence that persons had died as a result of using Abbott drugs was relevant to the grand jury's investigation of possible violations of the Act by Abbott and its employees.

The evidence was relevant because one possible violation of the Act within the scope of the grand jury's investigation was whether the Abbott drugs were misbranded within the meaning of Section 502(j) of the Act, 21 U.S.C. 352(j).[7] That Section states that a drug is misbranded "[i]f it is dangerous to health." Obviously, evidence that death or illness had resulted from the use of Abbott drugs was relevant to establish a danger to health. Moreover, the grand jury could properly consider the reports of death, the knowledge that Abbott officials had of the reports and the actions they took in the light of those reports, as a means of illuminating their roles in the company and in the distribution of the drugs.

It does not follow, however, that any given official's responsibility is dependent on his knowledge. Indeed, *United States* v. *Dotterweich*, *supra*, 320 U.S. at 281, makes clear that the 1938 Act "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing." The fact that this evidence was relevant in determining whether the Act had been violated and in assessing individual criminal responsibility under the Act does not make it a necessary element of the government's case in a criminal prosecution.

5. The fact that the FDA does not prosecute minor violations of the law should not be used to lower the standard of care required of distributors.

Park (Br., pp. 32-33) and Canners (Br., pp. 33-34) argue that the Act would not be weakened by a lower standard of liability, because the FDA does not prose-

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[7]Park is not charged with distributing a misbranded drug or device.

cute for every violation of the Act and often awaits a second or subsequent offense showing a continuing violation before instituting prosecution.[8] But the success of the FDA's informal enforcement procedures is, of course, dependent on the availability of the law's criminal sanctions when needed.

In any event, this contention fails to recognize the distinction between the statutory standard for criminal liability, and the prosecutorial discretion lodged in a law enforcement agency. In the 1938 Act, Congress established perhaps the highest standard of care ever imposed by law, because of the obvious critical importance of safe and wholesome food and drugs to the public health and welfare. At the same time, Congress recognized in Section 306 of the Act the essential role of prosecutorial discretion in enforcing that high standard of care. (See United States Br., p. 30-32.) Thus, the statutory scheme recognizes that, even though not all violators will be prosecuted, the strong deterrent effect of strict criminal liability still represents a major statutory enforcement mechanism.

None of the opposing briefs contends that the FDA has used its prosecutorial discretion arbitrarily or unwisely. The recent study sponsored by the industry-financed Food and Drug Law Institute forthrightly concludes that "our limited survey of unreported cases does not raise serious questions of the abuse of the [*Dotterweich*] doctrine." O'Keefe and Shapiro, *Personal Criminal Liability Under The Federal Food, Drug, and Cosmetic Act: The Dotterweich Doctrine*, 30 Food Drug Cosmetic L.J. 5, 43 (1975).

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[8]The FDA uses informal procedures and civil actions to enforce the law far more often than it uses criminal action. For example, in fiscal year 1973-1974 the FDA made 33,511 establishment inspections, issued 1,195 formal regulatory letters requiring compliance with the Act, handled 881 violations by voluntary recalls of the products, and recommended to United States Attorneys 419 seizure actions, 21 injunction actions, and 88 criminal actions.

6. Neither alternative methods of enforcement nor a lower standard of care are adequate to assure compliance with the 1938 Act.

Some of the amici (Food Chains Br., pp. 17-24; Canners Br., pp. 24-26, 29-34) contend that a lower standard of care is appropriate because the FDA has other enforcement techniques and because a lower standard will, paradoxically, result in better compliance with the law.[9]

Seizure and injunction, the other judicial remedies contained in the Act, only prevent future violations of the law. Absent the availability of strict criminal sanctions, food and drug manufacturers would have no incentive to seek out and prevent violations, since they could simply wait for an FDA inspector to find a violation before doing anything about it.[10]

The argument of one amicus (Canners Br., p. 25) that criminal responsibility should be limited to consequences known to, or reasonably foreseen by, the corporate official is premised on its refusal (see p. 2, *supra*) to acknowledge the statutory duty of a food distributor to seek out and prevent violations. Obviously a recognition of this affirmative duty is the first step toward better compliance with the 1938 Act. Conversely a lower standard of care, predicated on a refusal to recognize that duty, will inevitably lead to more widespread violations.

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[9]Canners (Br., pp. 3-6, 32-33) takes inherently inconsistent positions on this matter. It first contends that extensive delegation of authority is essential in modern industrial management, and then inexplicably argues that corporate officers could not isolate themselves from potential violations of the Act without becoming unable to function effectively in their executive positions.

[10]The FDA has only 1,000 inspectors who dedicate half their time to food inspection, to monitor more than 70,000 food manufacturing and warehousing establishments, 275,000 retail food stores, and 600,000 other food service establishments (principally restaurants).

The FDA's experience during the second half of the 1960's proved that only vigorous enforcement of the law, by all available means, will bring about compliance. For approximately a five-year period, the FDA reordered its priorities to emphasize the regulation of drugs and to reduce its surveillance of food sanitation. In this relatively short period of time there was a substantial deterioration in the sanitary condition of the food industry as a whole, as found in the 1972 GAO Report (see United States Br., p. 36). As a result of that report, Congress doubled the FDA's resources for food sanitation enforcement. In the past year, after this increase in enforcement, the FDA has found noticeable improvement in the sanitation conditions of food establishments.[11]

Respectfully submitted.

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Solicitor General.

MARCH 1975.

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[11]If the lower standard for criminal enforcement advocated by Park and the amici were adopted, the admission at trial of all evidence of prior violations should be permitted in order to establish the requisite "wrongful action," even if such action occurred outside the applicable statute of limitations. In the instant case, for example, not only should the letter and other pertinent evidence relating to the earlier violations that occurred at the Philadelphia warehouse be admissible, but also any earlier violative conditions should be admissible, to establish corporate and individual awareness, and thus the "wrongful action" urged by Park and the amici.

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BRIEF FOR SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

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BRIEF FOR SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

INTEREST OF AMICUS CURIAE

The Synthetic Organic Chemical Manufacturers Association ("SOCMA") is an industry association of 72 member companies engaged in production of synthetic organic chemicals. A number of such chemicals constitute or are used in products subject to regulation

under the provisions of the Food, Drug and Cosmetic Act of 1938, as amended ("the Act" or "the Food and Drug Act"), 21 U.S.C. §§ 301 *et seq.* (1972). SOCMA and its member companies thus have an interest in the interpretation accorded the Food, Drug and Cosmetic Act, and in even-handed, non-discriminatory enforcement of the provisions of the Act.

QUESTION PRESENTED [1]

Whether a doctrine of vicarious liability, in addition to the doctrine of strict liability approved in *United States* v. *Dotterweich*, 320 U.S. 277 (1943), should be read into the criminal penalty provisions of the Federal Food, Drug and Cosmetic Act to sustain the conviction of a corporate officer for violations of that Act.

STATUTE INVOLVED

The defendant at trial (respondent here) was charged [2] under Section 303 of the Federal Food, Drug

[1] In addition to the question of statutory construction (and underlying constitutional requirements) discussed in this *amicus* brief, the Government as petitioner has posed and addressed a second question which will not be dealt with by *Amicus*. This second issue is whether admission of evidence of an alleged prior criminal offense not the subject of conviction was prejudicial error.

[2] Substantively, the charges were based upon non-compliance with Section 301(k) of the Act, as amended, 21 U.S.C. § 331(k) (1972):

> The following acts and the causing thereof are prohibited:
>
> . . .
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

"Adulterated" is then defined by Section 402(a) of the Act, 21 U.S.C. § 342(a) (1972), as follows:

> A food shall be deemed to be adulterated . . . (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health . . . .

and Cosmetic Act, as amended, 21 U.S.C. § 333 (1972), which provides in material part:

> (a) Any person who violates a provision of section 331 [§ 301 of the Act] of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
>
> (b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

STATEMENT

By information, the United States charged a food store chain, Acme Markets, Inc., and its president, John R. Park, with violations of Section 301 of the Act, 21 U.S.C. § 331 (1972), based on the presence of rodents in Acme's Baltimore warehouse. Acme's headquarters, including Park's office, is in Philadelphia.

Prior to trial, Acme entered a plea of guilty to the counts of the information. The counts against Park were tried to a jury. On May 10, 1973, Park was found guilty, and subsequently he was fined a total of $250.

The trial was marked by controversy and disagreement over whether the jury should be instructed that Park's position as president of Acme was a sufficient factual predicate of "responsible relation" or "responsible share" in the violations for a finding of his personal guilt, under the interpretation given the Act in *United States* v. *Dotterweich,* 320 U.S. 277 (1943). Much of the Government's evidence at trial consisted of a reading into the record of Acme's by-laws insofar as they described the Acme President's duties. Consistent with this approach, the Government urged the trial court to adopt jury instructions which allowed the jury to find Park guilty based upon the theory of strict liability espoused in *Dotterweich,* coupled as well with application of a vicarious liability concept. Over strong objection, the trial court approved and gave instructions substantially in the form requested by the Government:

> *The main issue for your determination is . . . whether the Defendant held a position of authority and responsibility in the business of Acme Markets.*

The corporation, Acme Markets, Incorporated, has already entered a plea of guilty to the charge placed against it, and, while that plea does not imply, in any way, the Defendant Park is guilty, the fact that the materials in question are foods held for resale after shipment in interstate commerce and held under unsanitary conditions are issues that are beyond question in the case and must be accepted by you.

The statute makes individuals, as well as corporations, liable for violations. An individual is liable if it is clear, beyond a reasonable doubt, that the elements of the adulteration of the food as to travel in interstate commerce are present. *As I*

> *have instructed you in this case, they are, and that the individual had a responsible relation to the situation, even though he may not have participated personally.* (A. 61-62.) (Emphasis added.) [3]

The court of appeals reversed, holding that "a finding of guilt must be predicated upon some wrongful action by Park. That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which could 'cause' the contamination of the food". 499 F.2d 839, 842 (1974). The court of appeals rejected the Government's trial position that the Food and Drug Act authorized conviction of a firm's officer on the combined scourge of strict liability plus vicarious liability. As the court said respecting vicarious liability: "It is the defendant's relation to the criminal acts, not merely his relation to the corporation, which the jury must consider; 21

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[3] The Court continued:

> The individual is or could be liable under the statute even if he did not consciously do wrong. However, the fact that the Defendant is president and is a chief executive officer of the Acme Markets does not *require* a finding of guilt. Though, he need not have personally participated in the situation, he must have had a responsible relationship to the issue. The issue is, in this case, whether the Defendant, John R. Park, *by virtue of his position in the company,* had a position of authority and responsibility in the situation out of which these charges arose. (*Id.*) (Emphasis added.)

By adding its caveat that Park's position as president of Acme did not "require" a finding of guilt, the trial court seems to have said that it could not direct a verdict of guilty—*i.e.,* while Park's position did not "require" finding of guilt, the jury "may" or "could" make such a finding based upon Park's position as defined and elaborated in Acme's by-laws.

U.S.C. § 331 is concerned with criminal conduct and not proprietary relationships". *Id.* at 841.

The dissenter in the court of appeals had very little to say about the jury instructions, but he did refer to "the prosecutor's argument to the jury" in concluding "that there was no effort to equate the presidency of the corporation with the responsibility." *Id.* at 844 (Craven, J., dissenting). However, the dissenter demonstrated affirmatively that he was muddling vicarious liability concepts with those of strict liability:

> "I am sympathetic with my brothers' sense of justice that prompts them, it seems to me, to write into the statute some small degree of mens rea or scienter as a prerequisite to liability, but I share the government's fears that today's decision will undermine the congressional purpose of protecting 'the innocent public who are wholly helpless' to protect themselves from contaminated food." (*Id.* at 845.)

SUMMARY OF ARGUMENT

The court below separated the issue of vicarious liability from that of strict liability under the Act and correctly analyzed the decision of this Court in *Dotterweich* as requiring a factual nexus between the conduct of an officer of a company and the violation before holding the officer personally liable. *Dotterweich* interpreted the Food and Drug Act as dispensing with *mens rea* and thus imposed a strict liability for violations. However, the decision in that case made clear that to hold an officer liable, his conduct must bear a "responsible relation" to the offense. Dotterweich was in fact not only president and general manager but a straw boss who supervised a small group of employees who shipped the drugs in violation of the Act. When

this Court spoke of the factual basis for personal liability in this context, it referred to "acts" and "conduct" from which a jury could find the officer did "responsibly contribute" and had a "responsible share" and a "responsible relation" to the violation.

The trial court accepted the Government's theory of vicarious responsibility and under its instructions the jury could have found Park liable by reason of his position as president without any showing of factual nexus to the violation by conduct. The Government has now retreated minimally from its trial position of combining vicarious liability with strict liability and is asking the Court to endorse the unsound principle that the constitutional requirement that the Government prove its case beyond a reasonable doubt is satisfied by a showing of the title of an officer and the broad scope of his duties under company by-laws without any showing of personal acts or conduct which provide a factual nexus with the violation. It is up to the officer then, the Government proposes, to bear the burden of showing he was "powerless" in the situation.

The Court should reject the Government's attempt to misuse the phrase "responsible relation", which this Court used in *Dotterweich* to describe the requisite element of personal conduct or action, as a device for imposing vicarious responsibility. This case demonstrates the unsoundness of the Government's contention that the basic issue of vicarious criminal liability can be solved by trusting the discretion of the prosecutor.

ARGUMENT

Introduction

Each of the opinions filed by the court of appeals focus on the meaning of the phrase "responsible relation", in recognition of the fact that this expression embodied the concept in the *Dotterweich* case that an individual could be held criminally accountable if he has a "responsible share in the furtherance of the transaction which the statute outlaws . . . ." (320 U.S. at 284.) The Court in *Dotterweich* eschewed any attempt to construct a formula which defined "the variety of conduct whereby persons may responsibly contribute to furthering a transaction" forbidden by the Act (*id.* at 285), leaving explication of "responsible relation" to jury instructions depending upon the factual situation presented to the trial court. Whatever the circumstances, however, the phrase necessarily connotes a required nexus of a responsible contribution by the person charged to the alleged violation, not a relation merely to the corporation or other entity also alleged to have been a violator.

The Government in its brief on the merits in this Court appears to have retreated slightly from its trial position that the Food and Drug Act contemplates personal criminal liability based upon a combination of strict and vicarious liability precepts. Now, the Government appears to argue that the corporate officer's position may be a sufficient factual predicate for a finding of his personal guilt, and that the burden of proof then shifts to the officer to show that his powers within the company were too weak for such a finding:

> While the liability created by the 1938 Act is strict, it is not vicarious. The limits of the principle appear in its articulation: the corporate officer must

> stand in a responsible relation to the prohibited acts; a claim that he is "powerless" may "be raised defensively at a trial on the merits". *United States* v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91. (Brief for the United States at 14.)

In short, the Government now says the personal criminal susceptibility under the Food and Drug Act is based upon strict liability plus vicarious responsibility, subject to a "powerlessness" defense.[4]

A. Prior Opinions of the Court Do Not Sanction Application of the "Tyrannous Combination" [5] of Strict and Vicarious Liability

A precise and concise author has set out the attributes of strict and vicarious criminal liability:

> The distinction between strict and vicarious responsibility has never been properly explained by the judges . . . . The full difference is this: strict responsibility does not dispense with something like a personal actus reus, whereas vicarious responsibility does. Conversely, strict responsibility dispenses with the need for mens rea altogether, whereas vicarious responsibility does not dispense with the need for mens rea on the part of the servant. *The same statute may, of course, create both strict and vicarious responsibility. In that event, since the responsibility is strict, there will be no need to prove mens rea on the part of anyone; and since the responsibility is vicarious, there will be no need to prove an actus reus on the part of the accused master.* It may be hoped that such a tyrannous combination will be found to be rare. (Wil-

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[4] This "defense" speaks not to the vicarious responsibility issue, but appears to be a proposed exception to the strict liability precept. See *infra*, at 18 n. 9.

[5] Williams, *Criminal Law: The General Part*, 286 (1953).

liams, *Criminal Law: The General Part*, at 285-86 (1953) (emphasis added).)

Application of both strict and vicarious liability (or responsibility) runs against the grain of American principles of fairness in application of criminal laws. It is hardly surprising that the court of appeals in the present case cast aside the Government's strongly-pressed arguments and insisted upon personal "acts" or "conduct", whether of "commission or omission". (499 F.2d at 841-42.) No prior decision of this Court provided a mandate to the court of appeals to abjure its distaste for vicarious criminal responsibility ideas. Certainly when this Court reinstated Dotterweich's conviction twenty years earlier, it had before it facts which established Dotterweich's personal involvement in the Food and Drug Act violation, even though those facts were not set out at length in the statement of the case. See *United States* v. *Park*, 499 F.2d 839, 841 n. 3 (4th Cir. 1974), commenting upon *United States* v. *Dotterweich*, 320 U.S. 277 (1943). Similarly, in *United States* v. *Balint*, 258 U.S. 250 (1922), and *Morissette* v. *United States*, 342 U.S. 246 (1952), the accused's conduct was apparent; the question before the Court was one of strict liability and not vicarious liability.

In *United States* v. *Balint*, 258 U.S. 250 (1922),[6] the defendants were charged with having sold an opium derivative and a derivative of coca leaves in violation of the Narcotic Act of 1914. The question was whether knowledge was an element of the offense charged. The

[6] On the day it rendered the *Balint* decision, the Court also held in *United States* v. *Behrman*, 258 U.S. 280 (1922), that a licensed physician was strictly responsible under the Narcotic Act of 1914 for improper prescriptions.

Court rejected the argument that the absence of a scienter element deprived the accused of constitutional due process guarantees, relying upon *Shevlin-Carpenter Co.* v. *Minnesota*, 218 U.S. 57 (1910). It ruled that in the Narcotics Act of 1914 Congress had provided for strict liability.

Twenty years later, when in *United States* v. *Dotterweich*, 320 U.S. 277 (1943), this Court had before it the question of whether strict liability applied to the Food and Drug Act, it gave an affirmative answer in reliance upon *Balint:*

> The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct-awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. *United States* v. *Balint*, 258 U.S. 250. (320 U.S. at 280-81.)

In so doing, it affirmed the conviction of Dotterweich for two violations: shipping understrength digitalis tablets and shipping a cascara compound that conformed to specifications but included a reference to an ingredient that had, a short time before, been dropped from the National Formulary. Dotterweich was the president, general manager and straw boss of a very small company (26 employees) which purchased drugs from manufacturers, repackaged them under its own label, and shipped them to order to physicians.[7]

[7] The instruction cited by the Government (Brief for the United States, at 24) obviously was aimed at the evidence.

Mr. Justice Frankfurter's opinion for the Court majority in *Dotterweich* did not stop with the strict liability issue, however. The court of appeals had reversed Dotterweich's conviction by construing the reach of the Act's penalty section in light of the scope of a guaranty provision in the Act which immunized a recipient of a regulated product where the seller gave a guaranty of the innocence of the product. The Court rejected the limitation on the penalty provision, but recognized the concern of the court of appeals that the penalty provision "might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment". (320 U.S. at 284.) The Court's safeguard was found in its requirement that the accused have a definite personal nexus with the offense: "To speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty". (*Id.*) And, as the Court restated the point: "The offense is committed . . . by all who do have such a *responsible share* in the furtherance of the transaction which the statute outlaws . . . ." (*Id.*) (emphasis added.) The *Dotterweich* Court recognized the difficulty in describing who such a chargeable official might be:

> "It would be too treacherous to define or even to indicate by way of illustration the class of employees which stand in such a responsible relation. To attempt a formula embracing the *variety of conduct* whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress, . . . would be mischievous futility." (*Id.* at 285.) (Emphasis added.)

The Court thus purposefully left further definition of the term "responsible share" or "responsible relation" to future cases. For example, the Court noted that violations could be "furthered" by persons "standing in various relations to the incorporeal proprietor". (*Id.* at 283.) Nevertheless, in spite of imprecision in the term "responsible share", *Dotterweich* and the cases following it make it clear that the mere fact that an individual holds a position in an enterprise carrying with it broad supervisory and administrative power is not sufficient to impose criminal liability on that individual. Indeed, the Court pointedly referred to a "variety of conduct". (*Id.* at 285) And, it had used the term "responsible" in the opinion in connection with its explanation of the penalty provision's imposition of misdemeanor sanctions upon both corporations and individuals:

> But the only way in which a corporation can act is through the individuals who act on its behalf. *New York Central & H.R.R.Co.* v. *United States,* 212 U.S. 481. And the historic conception of a "misdemeanor" makes all those responsible for it equally guilty, *United States* v. *Mills,* 7 Pet. 138, 141, a doctrine given general application in § 332 of the Penal Code (18 U.S.C. § 550). (*Id.* at 281.)

The reference to *United States* v. *Mills,* 32 U.S.(7 Pet.) 430 (1833), is illuminating because that case is an early decision of this Court approving a misdemeanor charge for "advising, procuring, and assisting" a mail carrier to rob the mails. (*Id.* at 431.) Thus, the *Mills* case definitely spoke of responsibility in terms of conduct, and the Court in *Dotterweich* was indicating its adherence to that time-tested position.

Despite these references to "conduct" and "act" and the juxtaposition of "responsibly contribute", responsible share" and "responsible relation" with "advis-

ing, procuring, and assisting", some have read the Court's *Dotterweich* opinion as bearing on vicarious responsibility. For example, Professor Packer states:

> The court of appeals opinion had at least the merit of keeping separate two questions that it would confound analysis to blur: first, whether whoever was responsible for the shipment could be held criminally liable, notwithstanding the absence of culpability on his part (the issue of "strict liability"); and second, whether Dotterweich could be held criminally liable, notwithstanding his own lack of connection with the shipment (the issue of "vicarious liability"). It is obvious that the second issue is dependent on the first; if no one committed a crime, there was no crime for which Dotterweich could have been held vicariously liable. The underlying issue was whether the statute imposed strict liability.
>
> The opinion for the Court, by Mr. Justice Frankfurter, did not make the essential distinction between the issues of strict and vicarious liability. It is not paraphasing unfairly to say that the Court held that since the liability was strict it was also vicarious. (H. Packer, *The Limits of the Criminal Sanction,* at 124-25 (1968))

Professor Packer, however, focused on the Court's conclusion that the Act dispensed with *mens rea* and did not analyze the Court's references to "act", "conduct" and "responsible share" in relation to vicarious liability. Perhaps he was influenced by the lack of factual description of Dotterweich's activities in any of the opinions, but as the court of appeals pointed out in its *Park* opinion, Dotterweich was the president and general manager of a small company with twenty-six (26) employees and he had direct supervisory responsibility over the physical acts which resulted in the violation charged. (499 F.2d at 841 n. 3.)

Roughly ten years after *Dotterweich,* the strict liability issue arose again in *Morissette* v. *United States,* 342 U.S. 246 (1952). There, however, the Court held that failure to specify criminal intent in a statute punishing theft or conversion of government property by fine or imprisonment would not be construed as eliminating that requirement. As the Court phrased it, "the ancient requirement of a culpable state of mind" is as "universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil". (*Id.* at 250.) There also, the Court noted that imposition of criminal punishment for "public welfare offenses" without such criminal intent, where "penalties commonly are reasonably small, and conviction does no grave damage to an offender's reputation", was a development which "has not, however, been without expressions of misgiving". (*Id.* at 255-56.)

It would be "tyrannous" indeed for this Court to couple the strict liability concept approved with at least some "misgivings" in *Dotterweich* with vicarious responsibility principles. No majority of this Court has ever indicated a willingness to follow such a course, and the Court should not do so now.

B. The Trial Court's Instructions Impermissibly Reflected Application of Vicarious Responsibility Principles

A most serious excursion from the *Dotterweich* principles occurred in the trial court's instructions to the jury. As noted in the statement of the case, *supra,* at the Government's urging the trial court instructed the jury that it *could* infer the requisite responsible relation of Park to the violation simply from his position in Acme. After defining the elements

of interstate shipment and unsanitary conditions, the court stated the crucial third element of the charged offenses as—

> "Thirdly, that John R. Park held a position of authority in the operation of the business of Acme Markets, Inc.
>
> "However, you need not concern yourselves with the first two elements of the case. The main issue for your determination is only the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets." (A. 61.)

After this opening statement of the conduct element, the trial court told the jury that the accused would have the necessary responsibile relation to the violation "even though he may not have participated personally". *(Id.)* And, further, the charge told the jury that "the fact that the Defendant is [president] and is a chief executive officer of the Acme Markets does not *require* a finding of guilt" *(id.* (emphasis added)), implying from the context that it *may* lead to such a finding. In short, by its instructions, the Court may well have confused the jury into believing that since defendant was president, a "position of authority and responsibility", he *could* be held responsible for the violation *without more*. This instruction thus allows conviction on the basis of a vicarious responsibilty. It accordingly contravenes the *Dotterweich* requirements of "conduct" and "acts" (whether of commission or omission) before a "responsible relation" to the offense could be found.

There is sparse evidence in the record that Park did have a role in directing the regional vice-president for the pertinent area to correct the violation, and the Government properly emphasizes that evidence as a

good advocate. (Brief for the United States, at 7-8, 17.) Nevertheless, the Government's case-in-chief at trial on the issue of responsible relation was mainly concerned with a reading of the Acme by-laws describing Park's duties. *(Id.* at 6-7). Accordingly, the Government's evidentiary approach at trial emphasized the erroneous aspect of the trial court's instructions, rather than serving to ameliorate it.

In addition, the Government's choice of Park as the sole individual defendant in the face of possible involvement of a number of other Acme officials illustrates the capricious and invidious nature of the danger inherent in allowing principles of vicarious responsibility to creep into the criminal law. The record indicates that the Government was well aware of possible involvement in some way of at least the following several Acme officials: the executive vice-president for sales and operations, Mr. Hammel; the vice-president for engineering, Mr. Fahlhaber; the Baltimore Division vice-president, Mr. McCahan; and the sanitation inspection engineer, Mr. Bronsdon. Each of these persons had or could have had some brush with the specific Baltimore warehouse situation which was the subject of the criminal information. In the face of these possibilities, the Government chose only Park and offered no rationale for thus charging him, leaving as the only possible conclusion that they wanted the "head man" without regard to his actual relationship to the violation. [8]

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[8] Such an exercise of prosecutorial discretion was clearly done on a far too vague and suspect basis, allowing as it has in this case for one official to be selected at random for prosecution solely on the basis of his position within the firm. The prosecution in this case also demonstrates that "prosecutorial discretion" and governmental "good faith" cannot be relied upon as the sole vehicle through which *Dotterweich's* principles are carried out.

Correction of the erroneous path of both the Government's prosecution and the trial court's instructions is necessary. Minimally, the spectre of vicarious liability should be firmly banished. And, a further delineation seems in order. If this case and the commentator's expressions of concern are any guide, in these strict liability prosecutions elements of vicarious responsibility are all too likely to be muddled into trial court instructions shaped to meet the situation at hand with very few if any time tested models upon which to rely except the concept that "conduct" and "acts" are necessarily involved in a "responsible relation". In the absence of personal nexus to the situation resulting in the violation, the rationale for finding an official "responsible" disappears, and prosecution of him or her takes on an *in terroreum* aspect.

Further, the lack of a relationship between the official's activities and the violation raises the potential for serious due process problems in the course of any prosecution of the official. These problems could take the form both of a lack of notice of potential liability to an official who is exercising all due care, and of a failure to fulfill the constitutional requirement that the prosecution must prove all elements of the crime against the defendant. [9]

[9] The lack of parameters for the definition of "responsible" may all too often, as in this case, be construed as requiring that the defendant prove he was not "responsible", rather than the prosecution's bearing the burden of demonstrating that he was. The Government is not correct in its assertion that *United States* v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86 (1964), sanctions remitting an accused official to such a defense, where the accused would bear the burden of proof. *Wiesenfeld* dealt with the peculiar situation where a public storage warehouseman was charged with violating the Food and Drug Act by "holding" adulterated articles. The cryptic *Wiesenfeld* opinion seems to hold that the "powerlessness" of the warehouseman would be a defense to the strict liability aspect of the violation, and would allow a limited exception to that doctrine. The warehouseman did not contend that he had not engaged in the requisite conduct in actually "holding" the articles; this aspect of the *Wiesenfeld* case would have reflected vicarious liability principles. The Government's analysis of *Wiesenfeld* illustrates the danger in not clearly and sharply delineating vicarious responsibility from strict liability.

Of further concern is the deleterious effect this lack of a nexus between the violation and the official charged as "responsible" will have on the deterrence sought to be created by the imposition of strict liability. The strict criminal liability aspect of the public welfare laws was intentionally designed so that the potential of punishment would act as a uniquely "effective means of regulation", 320 U.S. at 280-281, which would ensure that "degree of diligence for the protection of the public which shall render violation impossible". *People* v. *Roby*, 52 Mich. 577, 579, 18 N.W. 365, 366 (1884). But obviously this regulatory mechanism is correctly described as "tyrannous" if applied vicariously against a corporate official whose normal exercise of duties bore no relationship to the area of operations in which the violation occurred. Therefore, if an official used due care in his regular course of activities~~activties~~ and the violation still occurred, he is not a "responsible" official who should have criminal penalties imposed upon him, for such penalties can serve no deterrent purposes.

The Government, in defense of respondent's contention in the court of appeals that the Government arbitrarily exercised its prosecutorial discretion, offers to this Court a rather detailed explication of its guidelines for bringing prosecutions of this sort. See Brief for the United States, at 31-32. The Government's

position seems to be that it has voluntarily imposed upon itself restraints pertaining to its determination of whether a suspect individual bears a "responsible relation" such that the person should be charged, but that these restraints disappear at trial and are not to be reflected in the trial court's charge to the jury. This anomalous result should be corrected.

The Government says its policy[10] is —

> to prosecute only those individuals who are in a position and who have an opportunity to prevent or correct violations but fail to do so. Officials who lack authority to prevent or correct violations, or who were totally unaware of any problem and could not have been expected to be aware of it in the reasonable exercise of their corporate duties, are not the subject of criminal action. Even if investigation discloses the elements of liability, and ~~indicates~~ that an official bears a responsible relation to them, the agency will not ordinarily recommend prosecution unless that official, after becoming aware of possible violations, often (as with Park) as a result of notification by FDA, has failed to correct them or to change his ~~man~~ managerial ~~agrial~~ system so as to prevent further violations. In those instances where prosecution is brought, it is brought for past as well as t[h]e most recent, violations. *Id.* at 31-32.) (footnote omitted)

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[10] The Government's policy guidelines respecting the substantive conditions justifying criminal charges, or as the Government's brief denominates them, the "FDA's standards for reference of cases to the Department of Justice for prosecution" (*id.* at 31), appear to be reasonable. As the Government reports them, they include "continuing violations of law (*e.g.*, continuing insanitary conditions in a food plant); violations of an obvious and flagrant nature (*e.g.*, food warehouse overrun with rodents, birds and insects, which contains plainly contaminated products); and intentionally false or fraudulent violations". (*Id.*)

The more restrictive elements of the Government's "policy" would seem to be logical candidates for defining the Government's burden of proof and for inclusion in an instruction which would give the jury some guidance respecting whether an individual defendant's conduct or acts provided the requisite personal responsibility for imposition of criminal sanctions. For example, in this case what facts are shown by the record indicate that Park had no personal involvement at all with the violations found by the FDA inspector in his initial December 1971 inspection of the older building in Acme's Baltimore warehouse complex. Park never should have been charged with the counts arising from the December 1971 visit. His "responsibility", if any, is purely vicarious. The violations stemming from the subsequent March 1972 inspection of the same warehouse *conceivably could* stand in a different posture. This record, however, is very sparse, showing primarily that Park received a letter from the FDA respecting the initial inspection and referred it to the responsible regional vice-president for corrective action. The sparse development of the record on Park's personal involvement for the second series of violations could have been prevented had the Government's trial theory been focused on "conduct" or "acts" whether of omission or commission, as *Dotterweich* requires, rather than on principles of vicarious liability. In short, the portion of the Government's policy which relates to personal involvement should be built into jury instructions, and the trial of the accused should be conducted on that basis. The Government is simply barking up the wrong tree when it puts forth its policy as an answer to claims that its prosecutorial discretion had been arbitrarily exercised, and then turns right around and advocates that the actual

criminal trial of the accused can proceed using vicarious liability precepts.

In the past, apparently the Government has not so vigorously embraced vicarious responsibility principles. At least other reported cases exploring the issue of criminal liability of corporate officials support the Court of Appeal's view that *Dotterweich* requires that a "responsible" corporate official be one whose activities had some nexus with the occurrence of the violation. These cases all involve prosecutions of corporate officials who either were normally present at the site where the violation occurred or whose fulfillment of his duties entailed regular, direct inspections of the processes in which the violation appeared. See, *United States* v. *Cassaro, Inc.*, 443 F.2d 153 (1st Cir. 1971); *Lelles* v. *United States*, 241 F.2d 21 (9th Cir. 1957), *cert. denied*, 353 U.S. 974 (1957); *United States* v. *Kaadt*, 171 F.2d 600 (7th Cir. 1948); *United States* v. *Hohensee*, 243 F.2d 367 (3rd Cir. 1957); *United States* v. *Diamond State Poultry*, 125 F. Supp. 617 (D. Del. 1954); *Golden Grain Macaroni Co.* v. *United States*, 209 F.2d 166 (9th Cir. 1953). Interestingly enough, the one case the Government points to as demonstrating that such a presence or involvement is *not* necessary, *United States* v. *Parfait Powder Puff Co.*, 163 F.2d 1008 (7th Cir. 1947), *cert denied*, 332 U.S. 851 (1948), is a case in which *no individual* corporate official was charged and the corporation itself was the only defendant. See Brief for the United States, at 26.

These cases, therefore, present a pattern which the Court of Appeals has correctly noted and followed as being required by *Dotterweich's* formulation of a "responsible" corporate official; that is, that a mere position of general authority and supervision in a corporation is never sufficient; to be held as "responsible" a demonstration must be made of the nexus between the actual functioning of a person occupying that position and the occurrence of a violation. The court of appeals' decision's analysis of the *Dotterweich* case is particularly apposite in this regard, revealing as it does that *Dotterweich* itself was a case following the pattern above where the charged official was physically present and *personally* and *directly* made the executive and supervisory decisions. Far from being the dilatory discussion misguidedly focusing on the issue of size, as the Government has characterized it (Petition for Certiorari for the United States, at 12), this presentation of the factual background of *Dotterweich* is the ultimate confirmation of that case's requirement of a construction and utilization of the term "responsible" based on the relationship between the violation and the official, and of the correctness of the court of appeals' reasoning and result.

CONCLUSION

The Government in its brief would have this Court embark upon the perilous course of infusing concepts of vicarious responsibility into the criminal penalty provisions of the Food and Drug Act. There such principles would tyrannically combine with the concepts of strict liability previously approved by this Court in *Dotterweich*. The vicarious responsibility spectre is made particularly malevolent because the Government has cloaked this idea by the billowing fabric of the strict liability doctrine.

The Court in *Dotterweich* used the phrase "responsible relation" as a shorthand for describing the requisite element of personal conduct or action. That short-

hand should not be perverted into a vehicle for employing the very vicarious responsibility ideas the Court in *Dotterweich* was trying to avoid, as the Court has always avoided them, at least to date.

This Court should identify and sort out the vicarious responsibility aspects of the facts and of the Government's position. Then, it should reject them firmly.

The decision of the court of appeals should be affirmed.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

UNITED STATES OF AMERICA,

Petitioner,

v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE GROCERY MANUFACTURERS OF AMERICA, INC. AS AMICUS CURIAE

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-215

UNITED STATES OF AMERICA,

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v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE GROCERY MANUFACTURERS OF AMERICA, INC. AS AMICUS CURIAE

INTEREST OF AMICUS CURIAE

The Grocery Manufacturers of America, Inc. (GMA) is a trade association of the leading manufacturers and processors of food and nonfood products sold in retail grocery outlets throughout the United States. GMA represents the interests of its member companies in administrative, judicial and legislative proceedings.

The food industry shares with the Food and Drug Administration (FDA) the goal of providing safe, wholesome,

nutritious and properly labeled foods. GMA and its members regard this industry as having a primary mission and responsibility for assuring the integrity of the food supplied to the nation's consumers.

To that end, GMA seeks to take a positive, constructive view of the roles and duties of its members in terms of compliance with the spirit as well as the letter of the law.[1]

The case at bar raises a vital issue regarding the definition and scope of potential criminal liability for corporate officers arising out of company violations of the Federal Food, Drug, and Cosmetic Act.

GMA's member companies have a direct, major interest in the resolution of this issue, since pertinent statutory provisions apply to all food processors. This Court's ultimate decision, therefore, will have a profound effect on all GMA members.

GMA and its members seek clear enunciation of fair, just and practical standards of criminal liability for affected individual corporate officers and employees under the Act as an incentive to effective compliance with the law.

In GMA's view, the court of appeals below provided strict but practical standards by requiring that individual criminal liability must rest on proof of the responsible individual's *own* "wrongful action," whether by deed or omission.

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[1] For example, GMA in March 1974 published "Guidelines for Product Recall," a comprehensive manual to assist companies in improving their procedures for undertaking voluntary product withdrawals for any reason. In 1974, GMA also joined FDA and six other food trade associations in publishing "Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses," and sponsored regional public seminars on warehouse sanitation for industry members.

By contrast, the Justice Department exploits the facts at bar to assert a vague "test of constructive participation" (Pet. 12), which would expose corporate officers to criminal prosecution at the bureaucratic discretion of enforcement officials without published "guidelines," "criteria," or "standards."

Such an authorization for harsh and arbitrary criminal prosecutions under the Federal Food, Drug, and Cosmetic Act, based on corporate status rather than individual "wrongful action" and shifting the burden of proving innocence to the accused, is offensive to established principles of fairness and justice and can serve no legitimate regulatory objective.

ARGUMENT

I. In Accord With This Court's 5:4 Decision In *United States v. Dotterweich* And The Requirements Of Due Process, The Court Of Appeals Correctly Held That A Corporate Officer Must Be Guilty Of "Some Wrongful Action" Which Contributes To The Violation To Be Criminally Liable Under The Federal Food, Drug, And Cosmetic Act.

The Federal Food, Drug, and Cosmetic Act imposes criminal penalties as one method of enforcing compliance with its public health purposes. 21 U.S.C. § 333. But as this Court has previously held, the Act's criminal provisions cannot be applied in disregard of constitutional requirements of due process and fundamental principles of criminal law. *United States v. Cardiff*, 344 U.S. 174 (1952).

The need for such constitutional safeguards is all the more critical where the Act's criminal sanctions may be applied vicariously to a corporate officer based upon violations of the Act by corporate employees outside of his direct and immediate supervision.

Accordingly, even more fundamental than the constitutional requirement that the law provide notice as to

"what persons are included or what acts are prohibited" (*id.* at 176), due process bars criminal conviction of an individual corporate officer absent proof of some wrongful conduct personally attributable to the corporate officer. *United States v. Dotterweich*, 320 U.S. 277 (1943).

Consistent with these due process requirements as well as an unbroken line of decisions by this Court, the court of appeals held that under Section 301 of the Act, "a finding of guilt must be predicated upon *some wrongful action* by [the corporate officer]" (Pet. App. 5A-6A) (emphasis added). Further elaborating, the court specified:

> "That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' the contamination of food." (*Id.* at 6A).

In seeking to overturn this strict standard of care, the Justice Department misreads the 5-to-4 *Dotterweich* decision as dispensing with *any* proof of "wrongful action" by the corporate officer, and shifts to the individual defendant the exculpatory burden of proving that he is personally "without power" to prevent or correct the violation (Br. 22).

As we shall show, however, the Justice Department's vindictive theory of *absolute* criminal liability for corporate officers, based on corporate status rather than personal action or omission, is defective because:

(1) *Dotterweich* held only that a corporate officer who stands in a "responsible relationship" to the violation is not immune from the Act's criminal sanctions.

(2) Neither *Dotterweich* nor the Act dispenses with the requirement of proof of "some wrongful action" by the individual criminal defendant.

A. *Dotterweich* Held Only that a Corporate Officer Who Stands in a "Responsible Relationship" to the Violation Is Not Immune from the Act's Criminal Sanctions.

Contrary to the Justice Department's effort to extend the Delphic *Dotterweich* 5:4 majority opinion to eliminate the element of "wrongful action," *Dotterweich* addressed and decided only the issue of criminal liability under the Act of corporate officers who act in behalf of their corporate employers.

The Court in *Dotterweich* reversed a court of appeals decision that a corporate officer is *not* criminally liable for his own acts in the course of his corporate duties where the corporation was acquitted. *United States v. Buffalo Pharmacal Co.*, 131 F.2d 500 (2d Cir. 1942). Thus, by a narrow 5-to-4 decision, the Court ruled that the Act permits *both* the corporation *and* the individual who *acts* for the corporation to be found guilty of the misdemeanor charged under the Act.

As stated by Mr. Justice Frankfurter for the majority:

> "But the only way in which a corporation can *act* is through the *individuals who act on its behalf* . . . . And the historic conception of a 'misdemeanor' makes all those responsible for it equally guilty, . . . a doctrine given general application in § 332 of the Penal Code (18 U.S.C. § 550) [now codified as 18 U.S.C. § 2]. If, then, Dotterweich is not subject to the Act, it must be solely on the ground that individuals are immune when the 'person' who violates § 301(a) is a corporation, *although from the point of view of action the individuals are the corporation.*" 320 U.S. at 281 (emphasis added).

Accordingly, the Court rejected immunity for individual corporate officers, citing the absence of an express grant of immunity in the statute:

> "To speak with technical accuracy, under § 301 *a corporation may commit an offense and all persons who aid and abet its commission* are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission — assuming the evidence warrants it — to the jury under appropriate guidance. *The offense is committed . . . by all who do have such a responsible share in the furtherance of the transaction* which the statute outlaws. . . ." 320 U.S. at 284 (emphasis added).

That this Court's *holding* in *Dotterweich* deals only with immunity for individuals was subsequently reaffirmed in *United States v. Wise*, 370 U.S. 405 (1962). In *Wise*, the Court ruled that a corporate officer is subject to criminal prosecution under the Sherman Act for knowing participation in violative acts in his representative capacity for the corporation:

> "This Court was faced with the *same problem in United States v. Dotterweich* . . . . The Court of Appeals reversed the conviction of a corporate officer on the ground that only a corporation was a 'person' within the Act. This Court reversed the Court of Appeals, rejecting substantially the same argument that is advanced by the appellee in this case. The reason for the rejection is equally applicable to the case at bar. *No intent to exculpate a corporate officer who violates the law is to be imputed to Congress without clear compulsion;* else the fines established by the Sherman Act to deter crime become mere license fees for illegitimate corporate business operations. Following *Dotterweich*, we construe § 1 of the Sherman Act in its common-sense meaning to apply to all officers who have a *responsible share in the proscribed transaction.*" 370 U.S. at 409 (emphasis added).

In short, the Court's holding in *Dotterweich* was that individual corporate officers were not *per se* immune under the Act. But *Dotterweich* did *not* spell out the standard of care which such officers must satisfy or just what acts or omissions by such officers constitute criminal conduct.

B. Neither *Dotterweich* Nor the Act Dispenses with the Requirement of Proof of "Some Wrongful Action" by the Individual Criminal Defendant.

Although not explicating the standard of care under the Act, *Dotterweich*, citing *United States v. Balint*, 258 U.S. 250 (1922), also observed that "such legislation dispenses with the conventional requirement for criminal conduct — awareness of some wrongdoing." 320 U.S. at 281.

While the Justice Department seizes upon that dictum as virtually the sole support for its position of *absolute* criminal liability for corporate officers and employees under the Act, *Dotterweich* never addressed the element of "wrongful action."

Actually, this much is clear from *Dotterweich*'s reliance on *United States v. Balint, supra*, which decided that *scienter* was not required for proof of a crime under the Harrison Narcotics Act. The Court concluded that Congress intended that *scienter* not be an element of the crime, holding that a seller of narcotic drugs, who "sells the inhibited drug in ignorance of its character" may be subject to criminal penalties. 258 U.S. at 254.

Moreover, the *Dotterweich* majority itself would plainly impose criminal liability under the Act only on proof of some "wrongful action."

Thus, the majority emphasized that the present Act essentially reenacted the Food and Drugs Act of 1906 with respect to the liability of corporations and their employees, with "deletion of words — in the interest of brevity and good draftsmanship." 320 U.S. at 282. Section 12 of that earlier statute stated, in pertinent part:

> "When construing and enforcing the provisions of this Act, the *act, omission, or failure of any officer, agent, or other person* acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be *the act, omission, or failure of such corporation, company, society, or association as well as that of the person.*" (Emphasis added).[2]

This language — which in pertinent part was set forth in the majority opinion, 320 U.S. at 281-82 — envisions the requirement of "some wrongful action" by an individual corporate employee as a prerequisite to criminal liability.

At other points, the *Dotterweich* majority opinion further indicates its understanding that "some wrongful action" must be proven. Thus, the opinion emphasized that the corporation acts only "through the individuals who *act* on its behalf," that "from the point of view of *action* the individuals are the corporation," and that Congress did not

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[2] The minority argued that the failure specifically to make corporate officers liable for the actions of their corporate employers in the 1938 Act indicates that Congress did not intend to impose such liability, and that Section 12 of the 1906 Act was intended simply to make the corporation liable for the illegal acts of its officers. *See, e.g.*, 320 U.S. at 287-91.

intend to exonerate corporate employees "involved in *acts* of disobedience" of the statute. 320 U.S. at 281, 283 (emphasis added). *Cf. United States v. Wise, supra*, 370 U.S. at 409 (liability related to the "acts of the corporate officer"). Further, the Court stated:

> "The Act is concerned not with the proprietary relation to a misbranded or an adulterated drug but with its distribution. In the case of a corporation *such distribution must be accomplished, and may be furthered, by persons standing in various relations to the incorporeal proprietor.*" 320 U.S. at 283 (emphasis added).

Similarly, the Court noted that the Act casts risks "upon all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor." 320 U.S. at 284. Elaborating with respect to situations involving corporations, the majority opinion referred particularly to those who "*aid and abet*" the commission of the crime. *Id.* And the opinion carefully pointed to those "who do have such a responsible share in the furtherance of the transaction which the statute outlaws." *Id.*

Above all, these passages from *Dotterweich* demonstrate that this Court did *not* intend to make corporate officers and employees criminally liable merely because of their status or positions within the corporation, without any personal causative relation *to the wrongful transaction.* Rather, the *Dotterweich* decision supports the conclusion of the court below that:

> "It is the defendant's relation to the criminal acts, not merely his relation to the corporation, which the jury must consider; 21 U.S.C. § 331 is concerned with criminal conduct and not proprietary relationships." (Pet. App. 5A).

Accordingly, the court of appeals correctly disposed of the Department's misapplication of *Dotterweich:*

> "The error here is that the Government has confused the element of 'awareness of wrongdoing' with the element of 'wrongful action'; *Dotterweich* dispenses with the need to prove the first of those elements but not the second." (Pet. App. 4A) (footnote omitted).

Nor does any other authority support the Department's spurious extension of *Dotterweich* to dispense with the essential element of "wrongful action."

The Department's key judicial precedents lend no support. In *Morissette v. United States*, 342 U.S. 246 (1952), this Court reversed a conviction for taking government property where the prosecution failed to prove the defendant's *criminal intent*. The court distinguished *Dotterweich* and *Balint* as cases in which "abandonment of the ingredient of *intent*" related to "the peculiar nature and quality of the offense." 342 U.S. at 259 (emphasis added). Those cases pertained to statutes that defined crimes that do not "require a *mental element*." *Id.* at 260 (emphasis added). *United States v. Freed*, 401 U.S. 601 (1971) (similar). And in *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86 (1964), this Court only noted that "[i]t is settled law in the area of food and drug regulation that a *guilty intent* is not always a prerequisite to the imposition of criminal sanctions." 376 U.S. at 91 (emphasis added) (dismissal of a *corporate* defendant reversed).

Likewise, the Department's legislative history (Br. 26-30) is limited to the question of "intent," not "wrongful action." The testimony of Charles Wesley Dunn, then GMA General Counsel, stated simply that "intent is not an essential ingredient of the offense" under the Act. *Hearings before a Subcomm. of the Senate Comm. on Interstate and Foreign Commerce on S.1190 and H.R. 4071*, 80th Cong., 2d Sess. 49 (1948). In light of the prevailing 1943 *Dotterweich* decision, a contrary view in 1948 would have been

surprising. But nothing in that statement, or other aspects of the legislative history, disavowed the minimal requirements of the prosecution's proof of the element of "wrongful action" as a prerequisite of individual criminal guilt.[3]

In sum, the issue of just what constitutes "wrongful action" by corporate officers was left open by *Dotterweich*, and was not dispensed with as an element of individual criminality under the Federal Food, Drug, and Cosmetic Act.

In this context, the court of appeals has properly interpreted the Act to require proof of "some wrongful action" as a prerequisite to criminal liability for corporate officers. As the court noted, the officer must have personally taken some "acts . . . which cause the adulteration of such food" (Pet. App. 4A). That "wrongful action," as further defined,

> "may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' the contamination of the food." (Pet. App. 6A).

Indeed, the court of appeals properly cautioned:

> "As a general proposition, some act of commission or omission is an essential element of

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[3] Actually, strong concerns exist as to the concept of criminal liability without "awareness of wrongdoing." *See e.g.*, Hall, J., *General Principles of Criminal Law*, 304-309, 342-351 (2d ed. 1960); *Developments in the Law—The Federal Food, Drug, and Cosmetic Act*, 67 Harv. L. Rev. 632, 694-96 (1954). However, that issue need not now be resolved by this Court, since the court below did not dispute the *Dotterweich* disavowal of the need for culpable intent. (Pet. App. 4A). While that interpretation may offend constitutional requirements of due process, that issue is not necessarily before this Court except insofar as the Department confuses wrongful intent with "wrongful action."

> every crime. For an accused individual to be convicted it must be proved that he was in some way personally responsible for the act constituting the crime." (Pet. App. 4A).

Actually, a lesser requirement for imposing personal criminality might will leave the Act constitutionally vulnerable. For in *Cardiff*, invalidating the Act's factory inspection provisions as constitutionally defective for imposing criminality "without fair and effective notice," this Court stressed that:

> "The vice of vagueness in criminal statutes is the treachery they conceal either in determining *what persons are included* or what acts are prohibited. Words which are vague and fluid . . . may be as much of a trap for the innocent as the ancient laws of Caligula." 344 U.S. at 176 (emphasis added).

Cf. Powell v. Texas, 392 U.S. 514, 533 (1968) ("criminal penalties may be inflicted only if the accused has committed some act. . . .").

II. The Justice Department's Contentions Would Expose Corporate Officers To Arbitrary and Harsh Criminal Prosecutions, Unnecessary For Any Legitimate Regulatory Objective.

While disavowing vicarious liability, the Justice Department would nevertheless expose corporate officers to criminal prosecutions largely on the basis of their corporate *status* rather than any identifiable act or omission on their part.

To be sure, the Department's brief eschews the doctrine of vicarious liability, asserting that the Act's liability is "strict" but "not vicarious" (Br. 14). On the other hand, the Department also claims that "the test of constructive

participation is official responsibility, whether the corporation be large or small" (Pet. 12).

Actually, the Department's brief heavily postures criminal liability on the accused's corporate status. According to the Department, the Act

> "makes responsible corporate officials criminally liable for failure to discover and correct insanitary conditions because they have the power and responsibility to prevent such conditions, and have failed to do so." (Br. 20).

Significantly, a "responsible relation" to the offense must be attributed to "officials who have the power and responsibility to prevent or discover and correct violations and fail to do so" (Br. 17). And while elsewhere the Department proposes to confine this liability to "responsible" officials within "their zone of responsibility" (Br. 21), objective indicia of such "responsibility" are nowhere defined.

Essentially, the Department's circular formulation would delete the element of "wrongful action" from the criminal offense, and shift the burden of exculpation to the accused officer once his corporate status appears. For, per the Department, criminal "responsibility" may be avoided by "allowing an apparently responsible corporate official to prove — *as a matter of defense* — that he is without power to affect the prohibited condition" (Br. 22) (emphasis added). Again, criminal liability remains "for the jury to determine in the light of his functions within the corporations and such *defensive matters* as he may raise at trial bearing on his power with respect to the violation" (Br. 23) (emphasis added).[4]

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[4] Surprisingly, and inconsistently, the Department's brief interpolates that "the government must offer proof of *actual supervisory responsibility relating to the prohibited conditions*" (Br. 25). This

(continued)

Such a doctrine, however, vests almost total discretion in enforcement agencies to prosecute top corporate officers for any violation of the Act by their business firms. The Act proscribes a host of derelictions to which criminal liabilities may attach under the umbrella criminal bans of § 301. So long as an "apparently responsible corporate official" (Br. 22) was shown to have an undefined "responsible relation" to such violations, he could become liable to criminal prosecution, with the issue of guilt or innocence going to a jury.

But such untrammeled prosecutorial discretion is not authorized by statute or controlling precedent.

As previously detailed, neither the Act nor this Court's precedents authorize or sanction the absolute criminal liabilities asserted by the Department. While dispensing with the concept of "awareness of wrongdoing" as a component of criminality in a narrow category of regulatory enactments, no such deletion of the requisite "wrongful action" was heretofore contemplated or authorized for inflicting criminal penalties on *individual* corporate officers and personnel. *See* discussion of *Dotterweich, supra.*[5]

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[4] *(continued)*
departure from the Petition's "constructive participation" doctrine (Pet. 12) parallels the court of appeals' rationale requiring "some wrongful action," since failure to take affirmative action or to exercise direct supervisory responsibility might be deemed gross negligence, inattention to corporate duty, or omission when done by the corporate official who is in fact responsible for sanitation.

[5] Inasmuch as no *individual* defendant was there involved, the Department's reliance (Br. 14, 19, 22-23) on *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, is gravely misplaced. In any event, the Court there noted:

> "We are here concerned only with the construction of the statute as it relates to the sufficiency of the information, and not with the scope and reach of the statute as applied to such facts as may be developed by evidence advanced at trial." *Id.* at 91.

Nor are the enforcement agencies' "criteria," "standards," "policy," "guidelines," or "reasonable discretion" (Br. 30-32) an acceptable substitute. In the first place, the FDA's "internal review" and "enforcement guidelines" are neither published nor reviewable. And FDA's so-called "hearing" granted to "suspects" is an act of administrative grace, not legally required (320 U.S. at 279), and lacking the most elementary procedural safeguards such as a right of confrontation.

Such *in terrorem* powers of criminal prosecution, unqualified by any prerequisite of personal "wrongful action" by the accused individual, are not germane to any legitimate enforcement objective.

The American food industry comprises companies of all sizes. Many larger corporations with operations in many states employ thousands of employees in hundreds of establishments throughout the country. Their top officials have corporate responsibility and authority over all or many segments of their firms' operations. Their policies cannot be personally implemented, directed and controlled at every stage down to those employees whose direct actions may result in some violation of the Act. Such officers must and do rely on their creation of adequate procedures, and the delegation of authority to responsible subordinate officials.

It is within the realities of this need for appropriate delegation of authority that the responsibility of top corporate officials must be measured. As the court below rightfully noted:

> "To hold [a president] *criminally* liable for the wrongful actions of each and every one of these employees by merely showing his position with the corporation is manifestly unjust, unfair and beyond the realm of reasonableness." (Pet. App. 5A).

Indeed, the imposition of absolute liability would have a "questionable effect when applied to such groups as distributors or manufacturers operating under high standards who, as a practical matter, cannot take further precautions." *Developments in the Law — The Federal Food, Drug, and Cosmetic Act*, 67 Harv. L. Rev. 632, 695 (1954).[6]

Yet, under the Department's theory, the top official of a corporation employing thousands of persons could become criminally liable for the acts of individuals over whom, as a practical matter, he has no personal, direct control. He would be vulnerable to acts of sabotage, vengeance, insanity, and plain negligence and stupidity by people far removed from his personal supervision or actual control.[7] An inadvertent labeling error or an aberrant short-weight package could be the basis of criminal prosecution. A second minor infraction could bring a felony conviction for the corporate officer. § 303(b), 21 U.S.C. § 333(b).

[6] Significantly, the General Accounting Office report cited by the Justice Department (Br. 36), which. on the basis of inspecting only 97 plants out of an estimated 60,000 food establishments (not including restaurants, retail stores and meat and poultry slaughtering and processing plants), concluded that sanitary conditions were deteriorating, recommended that Congress "consider amending the law to provide for *civil penalties* when food sanitation standards are violated." Comptroller General of the United States, *Dimensions of Insanitary Conditions in the Food Manufacturing Industry*. Report to the Congress, No. B-164031(2) at 4, 40, 42 (Apr. 18, 1972) (emphasis added). A similar civil remedy is suggested in the Harvard Law Review article. 67 Harv. L. Rev. at 696.

[7] Paradoxically, the Department's concept of absolute criminal liability could reach the Secretary of Health, Education and Welfare, the Commissioner of Food and Drugs and other top agency officials under this very same statute. Section 301(j) prohibits, on pain of criminal penalty, the unauthorized disclosure by any FDA employee of trade secret information acquired in the course of official duties. Since top agency officials exercise supervisory authority, they might be deemed to stand in the same posture as a corporate official under the Department's "constructive participation" test. (Pet. 12).

Nor would a requirement of some *personal* "wrongful action" encourage subterfuge by spurious delegations of real corporate authority. (Br. 37-38). The court of appeals' rationale could reach any instance of wrongful "omission," without exposing a corporate official to criminal prosecution by reason of his status rather than his personal deed or omission.

Most fundamentally, the Department's contentions offend established tenets of criminal justice.

First, the Department would obliterate the prerequisite of not only "awareness of wrongdoing" but also "some wrongful action" on the part of the accused individual. In practice, the Department would supplant individual "wrongful action" with corporate "status," a dangerous dimension of personal criminal liability. *Cf. United States v. Robinson*, 370 U.S. 660 (1962) (holding unconstitutional criminal statute punishing defendant's "status" as narcotics addict).

Second, the Department would effectively abrogate the presumption of innocence in criminal cases for corporate officials under the Federal Food, Drug, and Cosmetic Act, by shifting to them the burden of disproving personal guilt.[8] For under the Department's theory, "the test of constructive participation is official responsibility" (Pet. 12),

[8] At one point, the Department asserts that the individual officer's only defense is to show that he was "without power" to prevent or correct the violation (Br. 22). This extreme and vindictive contention is the equivalent of stating that any corporation president, who according to his corporate employer's by-laws is responsible for the operation of the business, can become criminally liable under the Act for all violations by the corporation.

Significantly, "Peter Barton Hutt, assistant general counsel of the Food & Drug Div. of the Dept. of Health, Education & Welfare, makes it clear that the only exceptions he has in mind are the presidents 'who spend their entire lives down in Florida and let some other guy run the company.' " *Business Week*, February 24, 1975, p. 102.

with guilt or innocence "for the jury to determine in the light of his functions within the corporation and such *defensive matters* as he may raise at trial bearing on his power with respect to the violation" (Br. 23) (emphasis added). But any presumptions or culpability arising from corporate officer status, even if present in the statute, which they are not, would pose substantial constitutional questions. *Cf. Tot v. United States*, 319 U.S. 463 (1943) (a statutory presumption is unconstitutional where there exists no rational connection between the facts proved and the fact inferred).

Finally, the Department would relate individual criminality to unpublished and unreviewable administrative "criteria," "guidelines," or enforcement "policy" (Br. 31-32), which are always subject to change without notice. But bureaucratic discretion and internal routines cannot satisfy this Court's admonition, in *Cardiff*, that "fair warning" is required as to "what persons are included or what acts are prohibited." 344 U.S. at 176.

Above all, per the opinion of the court of appeals, the prosecution, as always required under criminal law, must prove beyond a reasonable doubt that the accused individual has taken "some wrongful action" which has caused the violation. In the case of a corporate officer, the prosecution must also go forward and prove, beyond a reasonable doubt, that the officer was in fact in a responsible position with respect to the violation, *and* that he in fact acted or failed to act properly in light of his position in a manner which contributed to the violation of the Act.

As the court below correctly stated:

> "[T]he requirements of due process are intended to favor fairness and justice over ease of enforcement. We perceive nothing harsh about requiring proof of personal wrongdoing before

> sanctioning the imposition of criminal penalties." (Pet. App. 6A).

CONCLUSION

For the reasons stated above, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-215

UNITED STATES OF AMERICA, *Petitioner*

v.

JOHN R. PARK

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

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BRIEF *AMICUS CURIAE* OF THE NATIONAL ASSOCIATION OF FOOD CHAINS

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BRIEF *AMICUS CURIAE* OF THE NATIONAL ASSOCIATION OF FOOD CHAINS

STATEMENT OF INTEREST

The National Association of Food Chains, Inc. [hereinafter "NAFC"], submits this brief as *amicus curiae* because of the concern of its members with the matter before the Court. Both parties have given their consent to NAFC's participation, pursuant to Rule 42.2.

NAFC is a non-profit trade association whose approximately 200 members are engaged in the retail distribution of food and grocery products. The Association is composed of all the larger, most of the medium-sized and a cross-section of smaller food chains in the United States.

The members of the Association engage in numerous activities subject to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, including warehousing and distributing food products to individual stores. NAFC members are also extensively engaged in food processing activities such as the operation of dairies, bakeries, coffee plants, and canneries.

Members of NAFC have a substantial and continuing interest in the effective enforcement of the Federal Food, Drug and Cosmetic Act. It is to the obvious benefit of all food chains that the food which they purchase from suppliers and sell to customers is free from adulteration, handled under sanitary conditions and accurately labeled.

The case before the Court concerns the responsibility of top-level management for warehouse sanitation. In order to provide guidance to its members in this important area, NAFC has recently taken responsibility for coordinating the efforts of seven trade associations and the Food and Drug Administration of the Department of Health, Education and Welfare in the preparation and publication of Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses. These guidelines are attached as Appendix A. The Guidelines indicate the continuing efforts which NAFC and its members have undertaken to achieve compliance with § 301(k) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331(k).

The implications of this case, however, extend beyond the issue of warehouse sanitation and the application of § 301(k), 21 U.S.C. § 331(k). The decision in this case will have a direct impact on the extent of

criminal prosecution for all offenses under the Federal Food, Drug and Cosmetic Act [hereinafter "Act"]. As presented to the Court, the issue is whether or not an individual can be held criminally liable for a corporate violation of the Act where there is no evidence of his participation in the alleged violation.

NAFC does not question whether an individual employee should be subject to criminal sanctions under the Federal Food, Drug and Cosmetic Act, where through some act or omission on his part a food product is unlawfully adulterated or misbranded. Where, however, a corporate officer or other employee has diligently undertaken to establish and implement a comprehensive compliance program neither the statute nor prior cases require that he be convicted of a criminal offense. To the contrary, the underlying purpose of the Act, purity and accurate labeling of food, should encourage such comprehensive compliance. This purpose would be ill-served by a construction of the Act which would subject a company employee to criminal punishment for inadvertent, often unavoidable, violations without regard to the comprehensiveness of the compliance program which he has established or the diligence of his supervisory efforts.

NAFC's interest in this case, thus, derives from a basic conclusion that effective compliance with the Act will best be obtained by requiring a high standard of effort as evidenced, in part, by its warehouse sanitation guidelines. *See,* Appendix A. The Government's advocacy of an absolute criminal liability rule based solely on an individual's corporate position adds nothing to effective compliance and, in fact, may detract from it.

The decision of the United States Court of Appeals for the Fourth Circuit established a correct, practical, and equitable standard which will result in better compliance with the Federal Food, Drug and Cosmetic Act.

The decision of the Court of Appeals provides that an individual's criminal liability under § 303 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 333, must be based on his own acts or omissions which contribute to a violation. NAFC's members strongly urge that this standard be affirmed, both because it correctly interprets applicable law, and because it establishes a workable rule for compliance with the Act.

SUMMARY OF THE CASE

This action was initiated in the United States District Court for the District of Maryland by criminal informations against Acme Markets, Inc. [hereinafter "Acme"] and Acme's President, Respondent John R. Park. The informations were based on the presence of rodents in a portion of Acme's Baltimore warehouse. Acme, a large retail food chain employing approximately 36,000 persons in 874 retail outlets, has twelve main warehouses and four special warehouses.

The informations against Acme and Park contained five counts, four of them based on deficiencies noted during a Food and Drug Administration inspection in November-December 1971, and one based on a deficiency noted in a subsequent inspection in March of 1972. The corporate defendant, Acme, Inc., entered a plea of guilty to each of the five counts.

Prior to trial, Park filed a Motion for Bill of Particulars seeking the details of his alleged liability

for the violations. (Jt. App. at 10) The government responded to the motion by disclosing that the evidence would not show that defendant Park personally performed any of the acts described in the information, but that "the government's evidence will simply show that the defendant was a corporate officer who, under law, bore a relationship to the receipt and storage of food which would subject him to criminal liability under *United States* v. *Dotterweich,* 320 U.S. 277 (1943)." (Jt. App. at 14-15)

At Park's trial, the charge to the jury was given in substantially the form requested by the government and incorporated the same theory of liability set forth in the government's response to the motion for bill of particulars. After defining the elements of interstate shipment and unsanitary conditions, the trial court charged the jury to consider a third element:

> "Thirdly, that John R. Park held a position of authority in the operation of business of Acme Markets, Incorporated.
>
> "However, you need not concern yourself with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets." (Jt. App. at 61)

This portion of the charge to the jury, combined with other portions reflecting the view that criminal liability might exist without evidence of any wrongful action on the part of the Respondent, resulted in the Court of Appeals reversing. *United States* v. *Park,* 499 F.2d 839 (4th Cir. 1974).

In reversing Park's conviction, the Court of Appeals concluded:

> [A] finding of guilt must be predicated upon some wrongful action by Park. That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission of omission which would "cause" the contamination of the food. *United States* v. *Park, supra,* 499 F.2d at 842.

The Court of Appeals also concluded:

> It is the defendant's relation to the criminal acts, not merely his relation to the corporation, which the jury must consider; 21 U.S.C. § 331 is concerned with criminal conduct and not proprietary relationships. *United States* v. *Park, Supra,* 499 F.2d at 841.

The government petitioned for a writ of certiorari claiming that individual guilt may be based on "constructive participation," a test to be applied solely on the basis of the individual's formal duties and official responsibilities (Petitioner's Brief for Certiorari at 12).

SUMMARY OF ARGUMENT

I.

The decision of the Court of Appeals correctly interprets the applicability of criminal sanctions under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.,* and is consistent with the decision of the Court in *United States* v. *Dotterweich, supra.* Justice Frankfurter's decision in *Dotterweich* concludes that the Federal Food, Drug and Cosmetic Act is part of a class of legislation which ". . . dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing," *United States* v. *Dotterweich, supra,* 320 U.S. at 281. A person who violates this type of statute is subject to "strict" liability for

his violative act, whether or not he was aware that his action violated a regulatory standard. The Fourth Circuit correctly followed *Dotterweich* in concluding that while awareness of wrongdoing is not an element of the offense, Park could not be found guilty in the absence of "wrongful action" on his part. *United States* v. *Park, supra,* 499 F.2d at 841. *See* text 8-13, *infra.*

II.

Criminal liability for the acts of others must be based on the accused's participation in a criminal act, or his aiding and abetting in its commission. *See,* text 13-16, *infra.*

The government's position erroneously states the law by confusing the element of "awareness of wrongdoing" which need not be proved, with the element of "wrongful action" which must be found to hold Park as President of the company criminally liable. Until the government demonstrates that Park "participated" in causing a violation of the Act, he is not within the class of persons who may be subject to the Act's strict liability. The net effect of the government's position is to advocate that Park be held criminally liable by virtue of his office alone, which is a fundamental misconstruction of the Court's reasoning in *Dotterweich.* The government and the district court have erred in applying strict liability to Park without requiring proof of the casual connection, if any, between Park and the alleged violations. They have, thus, erroneously ignored controlling and traditional requirements of aiding and abetting which must be proved to establish vicarious participation in the wrongful action. *See* text 16-24, *infra.*

III.

The decision of the Court of Appeals would lead to more effective compliance with the Federal Food, Drug and Cosmetic Act than can be achieved through the standard urged by the government. The Court of Appeals has provided an incentive for managers to become responsibly involved in complying with the Federal Food, Drug and Cosmetic Act, and to build affirmative records demonstrating their care and diligence in exercising such responsibility. The government's standard would deter the involvement of corporate officials in compliance programs.

The decision of the Court of Appeals would make diligence a defense, while the standard of constructive participation urged by the government would make mere corporate position a crime. Successful compliance with the Federal Food, Drug and Cosmetic Act requires broad-scale and positive involvement of company managers and employees which would be encouraged by the Court of Appeals' standard. *See* text 17-24, *infra*.

ARGUMENT

I. THE DECISION OF THE COURT OF APPEALS IS CONSISTENT WITH THIS COURT'S DECISION IN *UNITED STATES v. DOTTERWEICH*.

The Court of Appeals properly recognized that:

> . . . For an accused individual to be convicted, it must be proved that he was in some way personally responsible for the act constituting the crime. The Supreme Court recognized this in *Dotterweich:* "The offenses committed . . . by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws

> . . ." *United States* v. *Park, supra,* 499 F.2d at 841 (4th Cir. 1974).

The Court of Appeals cited further language from *Dotterweich* in support of its decision:

> . . . To use the language of *Dotterweich,* "under Section 301 [21 U.S.C. § 331], a corporation may commit an offense and all persons who *aid and abet* its commission are equally guilty." *Id.* (Emphasis supplied by Court of Appeals.)

The government has relied on *Dotterweich* throughout its prosecution of Park. *Dotterweich* has been cited as authority by the government in its response to Park's motion for bill of particulars, its request for a charge to the jury and its petition for a writ of certiorari and its brief on the merits. The position enunciated by the government and incorporated by the district court in its jury charge is a misinterpretation of *Dotterweich*.

The government erroneously ignores the distinction set forth in *Dotterweich* between the "strict" liability for violations of the Federal Food, Drug and Cosmetic Act and "vicarious" liability of individuals for these violations. Strict liability is applied where awareness by the accused that his action was wrongful is not an element of the crime. Justice Frankfurter characterized the Federal Food, Drug and Cosmetic Act as a statute embodying this type of liability:

> . . . Such legislation dispenses with the conventional requirement for criminal conduct—awareness of wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in a responsible relation to a public danger. *United States* v. *Dotterweich, supra,* 320 U.S. at 281.

Although the Federal Food, Drug and Cosmetic Act establishes a standard of strict liability for determining whether individuals are criminally liable, this standard was carefully limited by Justice Frankfurter to individuals ". . . standing in a responsible relation to a public danger." *United States* v. *Dotterweich, supra,* 320 U.S. at 281.

While Mr. Justice Frankfurter held that an individual who has no "awareness of wrongdoing" could be convicted of violating the Federal Food, Drug and Cosmetic Act, he carefully defined those who might be subject to this strict liability as persons having the same causal relationship to the violation as described in section 322 of the penal code, 18 U.S.C. § 550 (1943) later codified in 18 U.S.C. § 2. *United States* v. *Dotterweich, supra,* 320 U.S. at 281 (1974).

Standards of liability for aiders and abetters in federal crimes are defined in 18 U.S.C. § 2:

> "(a) Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission is punishable as a principal.
>
> (b) Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal."

In *United States* v. *Dotterweich, supra,* the defendant had a close causal relationship to the violations charged since the defendant had *direct* supervisory responsibility over the *physical* acts which resulted in the violation. Joseph Dotterweich admitted personal involvement with and oversight of all the activities of Buffalo Pharmacal Company, Inc., the corporate de-

fendant.[1] The language of the *Dotterweich* decision which concluded that "awareness of wrongdoing" is not a necessary condition precedent for criminal conviction under the Federal Food, Drug and Cosmetic Act is addressed to the defendant's strict liability for acts in which he participated, not to his vicarious liability for acts in which he did not participate.

Dotterweich cannot be interpreted, as it has been by the government, to extend criminal liability to individual employees, absent any evidence of their personal participation in a violation of the Federal Food, Drug and Cosmetic Act. The Federal Food, Drug and Cosmetic Act imposes strict liability only on those who participate in violating the Act; it does not impose a unique standard of vicarious liability, absent aiding and abetting as defined in 18 U.S.C. § 2.

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[1] The Record which was before this Court in Dotterweich shows that not only was Mr. Dotterweich responsible for every aspect of the corporate defendant's busienss, but also that he testified in a manner which emphasized his personal responsibility. *See,* Appellant's Brief at 12, *United States* v. *Park,* 499 F.2d 839 (4th Cir. 1974) which states in pertinent part:

The violations charged in Dotterweich arose from two shipments of digitalis alleged to be less potent than required by law and a shipment of pills alleged to be misbranded. The evidence showed that the corporate defendant had been "created" by Dotterweich, in the words of defense counsel (R. 63), was owned by him, had approximately 26 employees, working on one floor of an office building, with Dotterweich as President, "General Manager," and the only supervisor. During the testimony by Dotterweich, his counsel almost invariably used the word "you" to refer to actions taken by other employees who worked under Dotterweich's supervision (R. 128, 141, 142). On cross examination, Dotterweich admitted that, "When I am in the place, I am in charge," and that he was "the boss," and that he must have been in charge on a day when one of the challenged shipments went out since he had signed a letter that day in his capacity as "General Manager" (R. 143-144).

The decision of the Court of Appeals in the present case is carefully consistent with *Dotterweich*. It explains that "strict" liability for violations of the Act is not at issue, *United States* v. *Park*, 499 F.2d *supra*, 840, n.2, and addresses the separate question of whether the charge to the jury in the District Court properly stated the law as to Park's liability as president and chief executive officer of Acme. The Court of Appeals found the charge incorrect since it would have allowed the jury to find Park guilty solely on the basis of his ". . . position of authority and responsibility in the business of Acme Markets . . . even though he had not 'personally participated in the situation'." *United States* v. *Park, supra*, 499 F.2d at 840.

The Court of Appeals properly perceived that ". . . the Government has confused the element of 'awareness of wrongdoing' with the element of 'wrongful action'; *Dotterweich* dispenses with the need to prove the first of those elements but not the second." *United States* v. *Park, supra* 499 F.2d at 841. The Court of Appeals further reasoned that, ". . . It is the defendant's relation to the criminal acts, not merely his relation to the corporation, which the jury must consider; 21 U.S.C. § 331 is concerned with criminal conduct and not proprietary relationships." *Id.*

The Court of Appeals correctly reversed Park's conviction since the jury could have based its verdict on Park's corporate position without considering his participation in the violative acts. The Court of Appeals' reversal is in harmony with the Court's decision in *Dotterweich*, which eliminated the need to prove awareness of wrongdoing, but which did not eliminate

the need to prove the accused's causal participation in the wrongdoing.

II. CRIMINAL LIABILITY OF A SUPERVISORY EMPLOYEE FOR VIOLATIONS OF THE ACT MUST BE BASED ON GROSS NEGLIGENCE. INATTENTION IN DISCHARGING CORPORATE DUTIES OR OTHER ACTS OF COMMISSION OR OMISSION WHICH CAUSE THE CONTAMINATION OF FOOD.

The basic issue presented by this case is the legal standard governing criminal liability of supervisory employees for violations of the law committed by subordinates. The government contends that a supervisory employee may be convicted for a violation occurring anywhere within the company on the basis of his position of authority. The Fourth Circuit holds that a supervisor may be found guilty only where he has participated in wrongful action.

The position of the government fails to provide a standard which juries can use in their deliberations.[2] On the other hand, the position of the Fourth Circuit provides a workable and legally sound standard for instructing juries on the possible criminal liability of company officers.

The present case involves the criminal liability of a general supervisor for the acts of subordinates. It is the type of liability which requires a causal connection between the supervisor's act and the alleged violation.[3] If supervisors are to be prosecuted under

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[2] The government's position is based on a fundamental misconception regarding the criminal responsibility of one individual for the acts of another. Such liability is "vicarious" and yet the government asserts that, "While the liability created by the 1938 Act is strict, it is not vicarious." (Brief for the Government at 14.)

[3] The desirability of holding supervisory officials vicariously liable for corporate violations of environmental standards is examined at length in Note, *Criminal Responsibility for Pollution of the En-*

section 301 of the Act, those prosecutions must be subject to the general standards for the imposition of criminal liability. These standards as embodied in the

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vironment, 37 ALBANY L. REV. 61 (1972). That article discusses Dotterweich's imposition of individual criminal liability for violations of the Federal Food, Drug and Cosmetic Act and advocates a similar standard for environmental legislation. The article goes on to describe the existing standard for vicarious liability as follows:

> The general rule is that an official will not be criminally liable for the acts of others within the corporation unless he participates in the act or aids and abets the criminal activity—3 Fletcher Cyc. Corp. § 1348 (1965); *State* v. *Flahe*, 83 S.D. 655, 165 N.W. 2d 55 (1969); *Clifton* v. *State*, 51 Del. 339, 145 A 2d 392 (1958); *State* v. *Pincus*, 41 N.J. Super. 454, 125 A 2d 420 (1956); *Hartson* v. *People*, 125 Colo. 1, 240 P 2d 907 (1952). 37 ALBANY L. REV. 61, 70.

The general rule recommended in this Note is compatible with the standard proposed by the Fourth Circuit. United States v. Park, 499 F.2d 839. (4th Cir. 1974) *See also* Sayre, *Criminal Responsibility for Acts of Another*, 43 HARV. L. REV. 689, 702-704 (1930). Sayre noted the importance of finding "causation" in those areas where criminal liability was based on the acts of another:

> "Vicarious liability is a conception repugnant to every instinct of the criminal jurist. It is not surprising, therefore, that courts today as a general rule . . . make criminal liability exclusively dependent upon causation. Causation may be proved either (1) by authorization, procurement, incitation or moral encouragement, or (2) by knowledge plus acquiescence. Apart from exceptional groups of cases . . . the law may be summarized as follows:
>
> (1) If the defendant can be shown himself to have counseled, procured, commanded, incited, authorized, or encouraged the commission of the particular act which forms the subject of the prosecution, all courts agree in holding him criminally liable, even though the agent committed the act through a different instrumentality, or at a different time, or in a different place from that ordered or authorized.
>
> (2) Where the defendant has neither authorized nor consented to the particular criminal act, even though he has authorized the general business in the course of which the act was committed, the defendant may be civilly, but is not, except as under (3), criminally, liable.
>
> (3) On the other hand, even if the particular criminal act has not been authorized or consented to, if it grows out of and is the proximate consequence of one that has been authorized or procured, the defendant is criminally liable, whether or not the agent is acting in the course of the defendant's business." Sayre, *Criminal Responsibility for Acts of Another*, 43 HARV. L. REV. 689, 702-704 (1930).

Court's decision in *Dotterweich* and further developed by Court of Appeals require a "responsible relationship" or causal connection between the wrongful act and the individual charged under the Act.

The decision of the Court of Appeals correctly states the law governing the vicarious liability of an individual employee for violations of the Federal Food, Drug and Cosmetic Act:

> . . . For an accused individual to be convicted it must be proved that he was in some way personally responsible for the act constituting the crime. *United States* v. *Park, supra,* 499 F.2d at 841.

The Fourth Circuit further concludes:

> Upon a subsequent trial the jury should be instructed that a finding of guilt must be predicated upon some wrongful action by Park. That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would "cause" the contamination of the food. *United States* v. *Park, supra,* 499 F.2d at 842.

The Court of Appeals correctly declared that, ". . . The question of causation is to be distinguished from that of intent." *United States* v. *Park, supra,* 499 F.2d at 842, n.7.

In holding that a supervisor's wrongful action must be causally related to a violation of the Federal Food, Drug and Cosmetic Act, before an individual may be held criminally responsible, the Fourth Circuit has enunciated a legally sound standard to be applied to cases involving "vicarious" liability. In the present case there is no allegation that Mr. Park counseled, procured, commanded, incited, authorized or encouraged the commission of the particular acts which forms the subject of the prosecution.[4] If Park is to be held vicariously liable, then it must be because his conduct falls within the category of vicarious criminal liability where:

> ". . . [E]ven if the particular criminal act has not been authorized or consented to, if it grows out of and is the proximate consequence of one that has been authorized or procured, the defendant is criminally liable . . ."[5]

The Fourth Circuit concludes that "gross negligence and inattention" are the kind of wrongful action upon which vicarious liability may be predicated; thus, finding supervisory employees responsible only for the "proximate consequences" of their actions. *United States* v. *Park, supra,* 499 F.2d at 842.

The standard of liability urged by the government is based solely upon the supervisory position of the defendant.[6] However, while the government suggests that this is not the standard it is advocating,[7]

[4] *See* Sayre, Note 3, *supra,* at 702.

[5] *See* Sayre, Note 3, *supra,* at 703-704.

[6] This standard based on corporate office-holding comes very close to the type of "status" offense held unconstitutional in California v. Robinson, 370 U.S. 660, rehearing denied 371 U.S. 905 (1962).

[7] "The majority of the Court of Appeals believed the government to be arguing 'that the conviction may be predicated solely upon a showing that the defendant, Park, was the President of the offending corporation'." (Brief for Government at 11.)

the only additional element which the government apparently views as a prerequisite for a conviction is the existence of a violation on the part of the corporate employer. The government apparently concedes that an accused may demonstrate his lack of power and responsibility as defense to alleged liability.[8]

The proper standard for determining the liability of a supervisor must turn on his causal connection to a wrongful act as enunciated by the Fourth Circuit. The *per se* standard of guilt by position urged by the government is contrary to law. The standard of criminal liability adopted by the Fourth Circuit, is correct and should be affirmed.

III. THE DECISION OF THE FOURTH CIRCUIT WILL RESULT IN MORE EFFECTIVE COMPLIANCE WITH THE ACT BY ENCOURAGING GREATER NUMBERS OF INDIVIDUALS TO BECOME INVOLVED IN SANITATION ACTIVITIES.

The standard for imposition of criminal liability established by the Court of Appeals will result in more effective compliance with the Federal Food, Drug and

[8] Brief for Government at 14. *See,* United States v. Wiesenfield Warehouse Co., 376 U.S. 86, 91 (1964). *See also,* Morisette v. United States, 342 U.S. 246 (1952), wherein Mr. Justice Jackson noted the limited applicability of strict liability to public welfare offenses. Mr. Justice Jackson raises the implication that strict liability is only appropriate where the accused has failed in a duty which he could reasonably be expected to perform.

> . . . The accused, if he does not will the violation, usually is in a position to prevent it with no more care than society might reasonably expect and no more exertion than it might reasonably exact from one who assumed his responsibilities. 342 U.S. at 256.

Cosmetic Act than will the standard urged by the government. Successful compliance with the Federal Food, Drug and Cosmetic Act requires the extensive and positive involvement of many individual employees. The standard announced by the Court of Appeals is more likely to encourage such involvement than the standard urged by the government, since it provides an incentive for individual employees to establish an affirmative record showing due care and diligence in complying with the requirements of the Act. The decision of the Court of Appeals will make diligence a defense, while the standard of liability by office urged by the government will make the mere holding of corporate office a crime.

The net effect of the Court of Appeals decision is to encourage individual employees and supervisors to become involved with programs of compliance under the Federal Food, Drug and Cosmetic Act. This extensive involvement is particularly important in complying with the Act's sanitation requirements since optimal compliance entails complex activities which, in most companies, cannot be handled by a single employee or even by a small group of employees. The complexity of a good sanitation program is indicated by the Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses.[9] The appendix to the Guidelines describes the commitment of personnel necessary for an effective sanitation program:

> To ensure product wholesomeness and proper sanitation, the food warehouse sanitation program must have the commitment of top management, must be implemented by operating supervision,

[9] Reprinted *infra* as Appendix A.

and must be supported by the entire food warehouse staff. Preventive sanitation—the performance of inspection, sanitation, building maintenance, and pest control functions designed to prevent insanitation in preference to correcting it—should be an important goal of food warehouse management and of food warehouse operations.

A program to ensure continued success in safeguarding the wholesomeness of food and in providing good sanitation will ordinarily include:

(1) An organizational chart showing chain of authority and responsibility.

(2) A flow diagram of receiving, storage, and shipping operations.

(3) Regular maintenance schedules.

(4) Regular sanitation programs.

(5) Regular pest control programs.

(6) An effective program of follow-up and control including reports to responsible executive officer(s)." Appendix A, *infra*, at 15a-16a.

An effective sanitation program must utilize the most modern techniques of management through quality control to systematically achieve product standards and eliminate defects. Management through quality control utilizes methodical inspection at various points in the manufacturing or distribution process to prevent defects and achieve higher quality standards than are obtainable by direct visual product inspection.[10]

[10] The genesis of quality control is described in J. HAGAN, A MANAGEMENT ROLE FOR QUALITY CONTROL, 62 (1968)

> "Quality control originated in inspection. So many defects were originally found in delivered products that inspection was established to screen good products from bad at the end

Preventive techniques, utilizing up-to-date methods of systematic quality control, are the best way to assure compliance with federal sanitation standards. The Voluntary Industry Sanitation Guidelines stress that "preventive sanitation" is preferable to the correction of insanitation and recommend regular maintenance schedules, sanitation programs and pest control programs, together with effective follow-up and reports to responsible executives. The management of this type of recommended sanitation program involves the coordination of a number of people. No one individual can personally sweep every floor or bait every rodent trap. The Court of Appeals by holding each individual liable for his own performance encourages individuals to become involved in compliance programs knowing that their individual responsibility for preventive activities must be diligently pursued.

The tasks of a manager have been defined by Peter Drucker, a leading authority on management techniques, to include: (1) setting objectives; (2) organizing to achieve those objectives; (3) motivating and communicating with employees; and (4) measuring the degree to which objectives are achieved and communicating those measurements to both subordinates and superiors.[11] All of these tasks are involved in the

of the production line, thus enabling the company to maintain an acceptable performance image and so continue to grow productively. Before long, when it became obvious that the rejected products represented an ever-increasing cost, inspection was extended to include points within the manufacturing process. This move was intended to prevent the manufacture of defective articles and was the start of quality control."

[11] P. DRUCKER, MANAGEMENT, 400 (1974).

management of a sanitation program. The objectives of meeting or exceeding federal sanitation standards are obvious. The organization necessary to achieve the objectives may take many forms. In every case, the success of that organization will depend upon the following integral factors: first, management's communication of program objectives to employees; second, employees' communication of barriers preventing the achievement of program objectives to management; third, on-going measurement of compliance progress.

Improved sanitation can only result from orderly and systematic management utilizing the latest quality-control techniques. The government, in describing courses of action open to Mr. Park, advocates procedures which are disorganized and unsystematic.[12]

[12] "There were a number of constructive actions [Mr. Park] should have taken. With the list of observations before him, he could have applied his own common sense to the situation and personally ordered corrective action. He could have, for instance, demanded that the warehouse be completely emptied and cleaned, that each lot of food be moved and checked thoroughly for rodents, and that the structure be thoroughly checked to make sure that all possible points of rodent entry be closed. Such measures are elementary methods of house cleaning.

"At the very best, respondent should have personally discussed with McCahan the list of observations item by item and ascertained precisely what McCahan would do about each. He could have demanded to know why the Baltimore facility had been allowed to deteriorate to the point that it had. He could have attempted to ascertain the amount of effort and money that would be necessary to insure that the premises would be cleaned up properly and offered McCahan whatever assistance was necessary. Any one or all of these things would have impressed upon McCahan the importance which he attached to the situation. He could also have instructed the appropriate corporate officials to utilize the resources necessary to remedy the situation. Certainly respondent could have followed up by calling McCahan and other corporate officials who handled sanitation problems to get personal briefings on the specific correc-

Even if a company employee took all of the uncoordinated measures suggested by the government, he would still be subject to criminal prosecution solely on the basis of his corporate position if any violative condition remained.

The decision of the Court of Appeals will have a salutary effect. Under that decision, an individual's failure to organize, communicate, or measure the success of sanitation efforts may constitute evidence sufficient to sustain a criminal conviction, while active efforts to improve sanitation will only create individual liability where such efforts causally contribute to violations of the Act.

Under the standard of liability by office urged by the government, an individual employee who takes part in communication and measurement of compliance is subject to criminal prosecution if any part of the compliance system fails, even where the failure occurs through no fault of the accused. This approach would deter individual employees from involving themselves in the communication and measurement process, which is necessary to achieve optimal sanitation standards. Orderly management requires the

tions being made. Indeed, given the fact that these same employees had already failed twice in the recent past, respondent could have retained a reputable outside consultant familiar with FDA requirements. Nor would it have been unreasonable for respondent to have personally visited the Baltimore warehouse to see for himself what progress, if any, was being made in correcting the situation. Finally, he could have closed the warehouse down unless and until he was personally satisfied that it had, beyond any doubt, been cleaned up. Given respondent's apathetic behavior, it is not surprising that the necessary steps were not taken and that many of the conditions went uncorrected until a criminal prosecution was instituted." (Brief for Government at 34, n.19)

active involvement of large numbers of employees. Active involvements is the government's own professed goal for the management of sanitation programs. Yet the standard of liability urged by the government would discourage involvement.

The Court of Appeals has correctly decided that the government's standard is not in accordance with settled doctrines of law. The government's standard is inherently unjust because it fails to distinguish between the criminal liability of an employee who exercises due care and diligence in carrying out his responsibilities and one who does not. The sole determinant of *per se* liability under the government's standard is whether any evidence of violation is discovered within an accused's formal scope of authority. No consideration is given to whether the accused had a role in causing that violation. Such an approach would provide an incentive to place responsibility for complying with the Federal Food, Drug and Cosmetic Act on the fewest possible employees rather than making such compliance an extensive, cooperative effort by many employees.

Although the government's policy of liability by office for Food and Drug Act violations can only be justified as a deterrent, there is no demonstration that this standard has been successful in the past.[13]

The Court of Appeals' decision, by requiring that the government prove that an individual act, or gross negligence, or inattention is causally related to the

[13] *See e.g.*, Comptroller General of the United States, *Dimensions of Insanitary Conditions in the Food Manufacturing Industry*, Report to Congress, No. B-164031(2) (Apr. 18, 1972).

violation, will encourage the greater involvement required for effective sanitation management. This potential for improved compliance is in furtherance of the Act's objectives and compels affirmation of the Court of Appeals' decision.

CONCLUSION

Therefore, the decision of the United States of Appeal for the Fourth Circuit should be affirmed.

Respectfully submitted:

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APPENDIX

APPENDIX A

VOLUNTARY INDUSTRY SANITATION GUIDELINES FOR FOOD DISTRIBUTION CENTERS AND WAREHOUSES

1974

Sponsored by:

ASSOCIATION OF INSTITUTIONAL DISTRIBUTORS
COOPERATIVE FOOD DISTRIBUTORS OF AMERICA
GROCERY MANUFACTURERS OF AMERICA
INTERNATIONAL FOODSERVICE DISTRIBUTORS ASSOCIATION
INTERNATIONAL FOODSERVICE MANUFACTURERS ASSOCIATION
NATIONAL-AMERICAN WHOLESALE GROCERS' ASSOCIATION
NATIONAL ASSOCIATION OF FOOD CHAINS

In cooperation with the
U. S. FOOD AND DRUG ADMINISTRATION

I. Foreword

These guidelines were prepared for receiving, handling, storage, and shipping of food and food products contained in retail and/or shipping containers at food distribution centers and food warehouse establishments, referred to as "food warehouses" throughout these guidelines. The term "food(s)" in these guidelines means foods and food products which are contained in retail and/or shipping containers, but includes items such as fresh produce received unpackaged or in partially open packages, which are subject to various specific additional portions of the guidelines.

The purpose of these guidelines is to promote receiving, handling, storage, and shipping of food and related items at such establishments in a manner that will assure the continued delivery of safe, sanitary, and wholesome foods to consumers.

It is further intended that conscientious adherence to the letter and spirit of these guidelines will not only minimize the chance of noncompliance with applicable governmental requirements for food sanitation, but will improve and maintain the overall effectiveness and quality of the practices by which foods are brought to the American consumer.

In this context, it is essential that management, including those directly responsible for any food warehousing activity, make provision for persons employed in a food handling capacity to receive the degree of training, emphasis, and support commensurate with their job responsibilities and with ensuring the effective implementation of the provisions of this document.

These guidelines, of necessity, are neither exclusive nor all inclusive; they are, however, intended to assist management and food warehouse operators in developing and maintaining facilities, methods, practices, and controls for

the receiving, handling, storage, and shipping of foods at the food warehouse establishment in a manner that protects the public health.

They are designed to deal with exposed or otherwise uncovered foods only to the extent that such foods are exposed or uncovered during receiving, handling, storage, and shipping in the food warehouse establishment.

They are not designed to cover food manufacturing, processing, or packaging areas and related equipment, practices, and procedures which are subject to regulations and/or guidelines specifically developed for those types of operations.

If food warehousing and food manufacturing, processing, or packaging operations are maintained in the same establishment, neither type of operation should interfere with the compliance with any good sanitation practices, guidelines, or regulations applicable to the other type or types of operations.

II. Buildings and Grounds

A. *Maintain Grounds Around Warehouses in a Sanitary Manner :*

- Maintain the grounds around food warehouse buildings under the control of the operator in a well-drained condition, and free from conditions likely to lead to contamination of foods in the food warehouse, leaving the food warehouse, or being delivered to the food warehouse.
- Keep grounds clean and free of discarded equipment, lumber, litter, waste, refuse, and uncut weeds or grasses within the immediate vicinity of the food warehouse which may provide breeding places or harborages for rodents, insects and other pests.
- Locate outside waste disposal containers on properly drained areas, clean them as needed, and keep them covered between use.

• Maintain and surface driveways, truck aprons, and rail sidings at receiving and shipping areas and parking areas to facilitate good drainage and to minimize dust and dirt being blown or tracked into the food warehouse. Maintain them in a clean, well-drained condition.

• If the food warehouse buildings are closely bordered by grounds not under the operator's control, exercise special care in the food warehouse, by inspection, extermination, or other means, to exclude and control pests, dirt, and other potential contaminants originating from such non-controlled grounds.

B. *Maintain and Operate Food Warehouse Buildings and Structures in a Sanitary Manner:*

• Provide floors and interior walls which are adequately cleanable and keep them clean and in good repair.

• Suspend fixtures, ducts, and pipes which are over working areas so as to prevent drip or condensate from contaminating food or food packages.

• Maintain adequate separation by location or other effective means for those operations which may cause contamination of foods with undesirable chemicals, filth, or other extraneous material.

• Provide adequate lighting to areas where food is received, stored, held or assembled for delivery, in order to facilitate handling, processing, and examination of merchandise and to permit adequate inspection, clean-up, and repair of the buildings and their structures.

• Provide adequate lighting in hand washing areas, dressing and locker rooms (if present), and toilet rooms.

• Employ appropriate special efforts to maintain sanitation whenever necessitated by unique features of structure or design.

• In a food warehouse utilizing light bulbs, light fixtures, skylights or other glass over exposed food, such as produce items in mesh bags, etc., use safety type bulbs or shielded fixtures to prevent food contamination in case of breakage.

III. Fixtures and Equipment

• Provide food warehouse equipment which is suitable as used and maintained, and is of design, material, and workmanship which permits it to be adequately cleaned and properly maintained by the methods used at the establishment.

• Use and maintain the equipment so as to prevent the adulteration of foods with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

• Install and maintain equipment in a manner which will facilitate its cleaning and the cleaning of adjacent spaces.

IV. Sanitary Facilities

Provide the food warehouse with adequate sanitary facilities and accommodations:

A. *Water Supply:*

• From an adequate source, provide a water supply which is sufficient for the food warehouse operations.

B. *Sewage:*

• Dispose of sewage into an adequate sewerage system or through other appropriate means.

C. *Plumbing:*

• Install and maintain plumbing of adequate capacity and design and in accordance with applicable governmental sanitation requirements, if any, so as to provide sufficient

quantities of water to required locations throughout the food warehouse, and to properly convey sewage and liquid disposable waste from the food warehouse.

D. *Toilet Facilities:*

• Provide toilet facilities which are adequate, kept in good repair, conveniently located, well-ventilated, and in compliance with applicable governmental sanitation requirements, if any.

• Provide them with self-closing doors and with walls, ceilings, and floors which are tight fitting and of a material which can be easily cleaned and kept in good repair; and maintain them in a clean condition.

• Furnish toilet rooms with toilet tissue, and post signs instructing employees to wash their hands with soap or detergent before returning to work.

• If toilet rooms are located near areas in the food warehouse where exposed foods, such as produce items in mesh bags, might be subjected to airborne contamination, provide them with self-closing doors which do not open directly into such areas.

E. *Hand Washing Facilities:*

• Provide adequate hand washing facilities in the toilet rooms or in places convenient to the toilet rooms for hand washing after use of the toilets.

• Furnish such facilities with hot and cold running water, hand-cleansing soaps or detergents, sanitary towels, or other suitable drying devices.

• Provide adequate receptacles, with covers, for disposal of hand-drying articles or waste material.

• Maintain the washing facilities and the surrounding areas in a clean condition.

F. *Dressing and Locker Areas:*

• If dressing and locker areas are present, provide them with adequate ventilation and lighting, and maintain them in a clean and orderly condition.

• If lockers are present, provide them with sufficient ventilation to keep them dry for the retardation of mold and odors and maintain them in a clean condition, free from trash, food scraps, or litter which serve as insect or rodent attractants. Keep the tops of such lockers clean, and do not use them as surfaces for the storage of materials.

G. *Eating Areas:*

• If there are eating areas in the food warehouse, enclose them adequately or locate them in areas away from operations. Provide adequate space, light, and ventilation in such areas. Clean eating areas regularly, and provide them with a sufficient number of covered receptacles for disposal of meal trash. Clean such trash receptacles regularly and do not permit them to become insect or rodent attractants.

• Clean and inspect vending machines and surrounding areas at regular and frequent intervals to detect and correct conditions of insanitation which may exist in or around such machines.

• If drinking fountains are provided, locate them conveniently and clean them regularly.

V. Sanitary Operations

A. *Keep Buildings and Equipment Sanitary:*

• Maintain buildings, fixtures, equipment, and other physical facilities of the food warehouse in good repair and in a sanitary condition.

• Conduct cleaning operations in such a manner as to minimize the danger of contamination. For cleaning and

sanitizing procedures, utilize detergents, sanitizers and other supplies which are safe and effective for their intended uses.

• Exclusive of packaged products held for distribution, store and use in the food warehouse only such toxic materials as are required for necessary activities, such as for maintaining sanitary and pest free conditions, for use in laboratory testing procedures, or for food warehouse and equipment maintenance and operation. Identify and use such products only in such manner and under such conditions as will be safe for the intended use.

• Use pesticides only under such precautions and restrictions as will prevent the contamination of food and food packaging materials.

B. *Rubbish:*

• Convey, store, and dispose of rubbish in a manner which will minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of warehoused food, food containers, ground surfaces, and water supplies.

C. *Pest Control Programs:*

• Establish and maintain positive control programs designed to exclude and eliminate pests from the food warehouse and to deny them harborage, in order to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects).

• Keep trained security dogs out of actual storage areas to avoid excreta contamination of foods stored at floor level. Keep cats out of the food warehouse.

• Implement these programs as an integral part of the construction, maintenance, operational, and personnel programs described elsewhere in the guidelines.

VI. Procedures and Controls

Conduct operations in the receiving, inspecting, transporting, handling, segregating, recouping, and storing of foods in accordance with appropriate sanitation principles. Implement overall sanitation under the supervision of an individual assigned responsibility for this function.

Take reasonable precautions, including the following, to assure that food warehouse procedures do not contribute to contamination of foods by harmful chemicals, objectionable odors, or other objectionable materials.

A. *Incoming Product Shipments:*

The integrity of the food warehouse sanitation program requires that the materials, including foods and their packaging, which are received into the warehouse do not expose the food warehouse to contamination by reason of infestation by insects, birds, rodents, or other vermin, or by introduction of filth or other contaminants. It is often useful, when practicable, to work with suppliers and shippers in advance to establish guidelines for acceptance, rejection, and where appropriate, reconditioning of particular product, taking into consideration factors such as the nature, method of shipment, and ownership of the product, in order to facilitate the effective implementation of these programs.

1. Within a reasonable time after the arrival of a car or truck, and before product is unloaded, the product should be inspected to the extent permitted by the loading of the vehicle for evidence of damage or of insect or rodent infestation, objectionable odor, or other form of contamination.

Where an adequate inspection has not been possible prior to unloading, further inspect such product during and immediately after unloading.

2. If damaged product has been accepted, keep it separate from other product, and recondition or otherwise handle it as necesary in a manner which will not expose foods or the food warehouse to contamination or infestation.

3. If the inspection reveals evidence of infestation or contamination:

• Determine whether the condition is only "suspect," or is superficial (such as surface infestation of flying insects which may be on, but have not penetrated, soiled, or compromised the integrity of the packaging) and might be fully correctable by fumigation or other means.

• In each such case, remove the product from the food warehouse area, utilizing the vehicle in which it arrived, if feasible, after closing and sealing it.

• In case of contamination, if rejection is appropriate (based on the origin and ownership of the product), promptly notify the carrier and shipper of the time, place, and circumstances of the rejection.

• After removal from the food warehouse because of suspect and/or superficial conditions, concentrated efforts can be made to further evaluate the actual condition of the product, and to recondition it, when possible.

4. Give special attention to product which has previously been rejected, or has otherwise been removed from the food warehouse because of suspect and/or superficial conditions, when it is subsequently received again, to assure that the product and packaging are fully acceptable on reinspection.

5. In the event of serious question, or of failure to agree with the shipper or carrier, as appropriate, as to condition or reconditioning, consider requesting evaluation of the suspect or rejected product by appropriate federal, state, or local authorities.

B. *Store Product Properly:*

• Place foods received into the food warehouse for handling or storage in a manner which will facilitate cleaning and the implementation of insect, rodent, and other sanitary controls and will maintain product wholesomeness.

C. *Proper Stock Rotation:*

• Adopt and implement effective procedures to provide stock rotation appropriate to the particular food.

D. *Contaminated or Damaged Foods:*

• Unless promptly and adequately repaired or corrected at or near the point of detection, promptly separate foods which are identified as being damaged or are otherwise suspect from other foods for further inspection, sorting, and disposition.

• Promptly destroy or remove from the food warehouse product determined to present a hazard of contamination to foods in the food warehouse.

E. *Hazardous Non-Food Products:*

• Handle and store non-food products which present hazards of contamination to foods stored in the same food warehouse by reason of undesirable odors, toxicity of contents, or otherwise, in a manner which will keep them from contaminating the foods.

• Take special measures to safeguard from damage and infestation those foods which are particularly susceptible to such risks.

F. *Avoid Damage to Packaging:*

• Exercise care in moving, handling and storing product to avoid damage to packaging which would affect the contents of food packages, would cause spillage, or would

otherwise contribute to the creation of insanitary conditions.

G. *Shipping:*

• Prior to loading with foods, inspect rail car and truck and trailer interiors for general cleanliness and for freedom from moisture; from foreign materials which would cause product contamination (such as broken glass, oil, toxic chemicals, etc.) or damage to packaging and contents (such as boards, nails, harmful protrusions, etc.); and from wall, floor, or ceiling defects that could contribute to insanitary conditions.

• Clean, repair, or reject them as necessary to protect foods before loading.

• Exercise care in loading foods to avoid spillage or damage to packaging and contents.

• Maintain docks, rail sidings, truck bays, and driveways free from accumulations of debris and spillage.

H. *Warehouse Temperatures:*

• Maintain warehouse temperatures (particularly for refrigerated and frozen food storage areas) which are in compliance with applicable governmental temperature requirements, if any, for maintaining the wholesomeness of the particular foods received and held in such areas.

I. *Housekeeping, Sanitation and Inspection:*

• Establish a regularly scheduled program of general housekeeping, sanitation, and inspection to maintain floors, walls, fixtures, equipment, and other physical facilities in a state of sanitation sufficient to protect foods from contamination or adulteration, and to prevent waste from becoming an attractant and harborage or breeding place for vermin.

• In addition, develop and implement an effective program and procedure for timely cleanup of any debris and spillage resulting from accidents or other unscheduled occurrences.

J. *Pest Control Measures:*

• Implement pest control measures designed to prevent the entrance of pests, to deny them harborage, and to detect and eliminate them, with such schedules, instructions, and procedures, and by such trained and qualified personnel or professional representatives as may be necessary, based on the nature of the foods and other products handled, the structure and condition of the building and equipment, and the surroundings and environment of the warehouse.

• Monitor traps and bait stations, whether inside or outside of buildings, on a regular basis. Use covered interior bait stations designed, located, or protected to prevent spillage. Where appropriate, use bait stations constructed of moistureproof material.

K. *Pesticides:*

• Use only pesticides with labels showing USDA or EPA registration numbers, and only for the uses specified in the labeling.

• Have them applied only by responsible personnel in accordance with the manufacturer's labeling instructions and in a manner which prevents contamination of foods. While not in use, clearly mark and store pesticides in a secure place apart from foods.

L. *Audit Food Warehouse Sanitation Programs:*

• Establish programs internally and/or through outside consultants for effectively auditing the food warehouse sanitation program.

VII. PERSONNEL

A. *Employee Practices:*

• Prohibit employees affected by disease in a communicable form, while carriers of such disease, or while afflicted with boils, sores, infected wounds, or other abnormal

sources of bacterial infection, from working in the food warehouse in capacities in which there is a likelihood of food becoming contaminated, or of disease being transmitted to other persons.

• Prohibit clothing or other personal belongings from being stored and food and beverages from being consumed and tobacco from being used in areas where foods are handled or stored.

• Instruct employees who are working in direct contact with exposed or partially exposed foods, such as produce items in mesh bags, etc., to maintain personal cleanliness and to conform to hygienic practices to avoid contamination of such foods with microorganisms or foreign substances such as human hair, perspiration, cosmetics, tobacco, chemicals, and medicants and, if gloves are used in handling such foods, to use only gloves which are of an impermeable material in handling such foods, and to maintain them in a clean and sanitary condition.

B. *Management Responsibilities:*

• Assign responsibility for the overall food warehouse sanitation program and authority commensurate with this responsibility to persons who, by education, training, and/or experience are able to identify sanitation risks and failures and food contamination hazards.

• Instruct employees in the sanitation and hygienic practices appropriate to their duties and the locations of their work assignments within the food warehouse. Instruct employees to report observations of infestations (such as evidence of rodents, insects or harborages) or construction defects permitting entry or harborage of pests, or other developments of insanitary conditions.

• Exercise programs of follow-up and control to ensure that your employees, consultants, and outside services are doing their jobs effectively.

Appendix

This appendix to the Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses has been prepared to assist the food warehouse operator in implementation of Sections (I) through (VII) of the *Guidelines.* Information in this appendix will require adaptation for specific application to your operations.

Since no single document can provide all the information necessary for every situation or specify the only methods for compliance, develop your own appendix or company guidelines to reflect your individual applications in the general areas dealt with in the *Guidelines* and this appendix.

I. Foreword

To ensure product wholesomeness and proper sanitation, the food warehouse sanitation program must have the commitment of top management, must be implemented by operating supervision, and must be supported by the entire food warehouse staff. Preventive sanitation—the performance of inspection, sanitation, building maintenance, and pest control functions designed to prevent insanitation in preference to correcting it—should be an important goal of food warehouse management and of food warehouse operations.

II. Organization and Programs

A program to ensure continued success in safeguarding the wholesomeness of food and in providing good sanitation will ordinarily include:

1. An organizational chart showing chain of authority and responsibility.

2. A flow diagram of receiving, storage, and shipping operations.

3. Regular maintenance schedules.

4. Regular sanitation programs.

5. Regular pest control programs.

6. An effective program of follow-up and control including reports to responsible executive officer(s).

III. Check Points and Additional Guides

1. *Grounds:*

• Keep nearby grounds free of liquid or solid emissions that could be sources of contamination.

• Prevent grounds from providing conditions for insect or rodent harborage.

• Check paving, drainage, weed, and litter control regularly.

• Stack materials which are stored in the open neatly and away from buildings, and on racks above ground level where feasible.

• "No-vegetation strips" around exterior building walls and at property lines adjacent to properties containing potential harborages are helpful for discovering and discouraging travel by rodents.

2. *Buildings:*

• Provide separate and sufficient space for placement of equipment and storage of materials necessary for proper operations.

• Separate activities that might cause contamination of stored foods with chemicals, filth, or other harmful material.

• Check structural conditions, pest barriers, repair of windows, screens, and doors continuously.

• Seal and clean floor wall junctions and fill holes and cracks; a painted inspection strip is also recommended.

• Keep offices—including overhead offices—in the food warehouse clean, and do not permit them to become attractants or harborages for insects or vermin. Include them in the pest control program.

• Check false ceilings for harborage of insects and possibly rodents.

• Give basements, attics, elevators, and rail sidings, etc., special attention.

3. *Sanitary Operations:*

• Keep walls, ceilings and rafters free of soil, insect webbing, mold, and similar materials.

• Do not leave unscreened doors and windows open unnecessarily.

• Do not permit dust to accumulate.

• Keep floors free of product spillage, oil drippage, and buildup in all areas.

• Provide proper trash and refuse storage and removal.

• Store tools and equipment properly.

• Clean and flush drains regularly.

• Maintain railroad and truck courts free of debris, and properly patrol them for pest control.

• Keep eating and break areas, locker rooms, etc. clean and orderly. Vending machines are often overlooked: keep them and the areas adjacent to them clean and sanitary. Maintain equipment in a properly functioning condition and do not permit it to serve as a source of sanitation or harborage problems.

4. *Receiving and Inspection:*

• Inspect the materials which are being received for evidence of damage; insect, bird, rodent, or other vermin infestation; and moisture, odor, or chemical contamination.

• Exclude contaminated materials, including product, pallets, and slip sheets, from the building.

• If damaged merchandise is accepted, segregate it for special handling.

• Make sure that incoming and outgoing vehicles are free of conditions that could contaminate product—no birds, rodents, insects, spillage, or objectionable odor should be evident.

• Code or mark foods received at the receiving point to ensure proper stock rotation.

• To facilitate handling of rejected and suspect product, it is often a good idea to develop procedures with individual shippers, carriers, and/or manufacturers for reinspections, returns, etc.

5. *Storage:*

• Store products in an orderly manner and so that date codes are visible for proper rotation.

• Generally, it is desirable to stack foods on pallets or racks (or on slip sheets, where a clamp truck operation is utilized), and away from walls so as to allow for inspection aisles between stacks and walls. Painting inspection aisles in a light color is often helpful in maintaining their effectiveness. Where full inspection aisles are not provided, take special care (such as more frequent inspection, rotation, and removal of product for cleaning) to ensure sanitary, pest free conditions.

• Separate bagged and baled foods to provide visibility between stacks.

• Dispose of contaminated or infested merchandise, or otherwise remove it from the food warehouse promptly.

• Promptly remove damaged merchandise and broken containers from general food storage areas. Handle and process salvageable merchandise separately in an area isolated from general food storage; this area probably will require extra sanitation and pest control attention.

• If salvage operations include the repackaging or other manipulation of exposed foods (other than items such as fresh produce received unpackaged or in partially open packages), conduct such operations in compliance with the food sanitation practices, guidelines, or regulations, such as 21 CFR 128, which are applicable to handling exposed foods.

• Do not intermingle chemicals, including pesticides, with food or food products. Such products are best separated by an aisleway.

6. *Pest Control:*

• Maintain written schedules, log activity, and monitor traps and bait stations regularly.

• Use covered bait stations which are of such types and so located as to reduce the danger of spoilage; and where appropriate, use moisture-proof bait stations.

• Keep the pesticides which are used in the food warehouse securely, and separate from foods. Permit their use only by properly trained personnel. Use only types registered and approved by an appropriate government agency for the intended use.

• Check especially for:

  • rodent burrows in nearby grounds,

  • activity at floor wall junctions and doorways, and

- insect crawl marks in dust accumulation, especially on overhead pipes, beams, window sills, around flour, sugar, and pet food storage.

• Where feasible, seal load levelers at docks to prevent trash accumulations and rodent harborage and entry; and clean them frequently.

• Look for insect activity in folds of bagged foods.

• Use black light, supplemented with means for distinguishing other chemicals that fluoresce, to check for rodent urine stains; and use flashlights to check for other evidence of contamination.

7. *Shipping:*

• Make sure that transportation equipment into which food warehouse food is loaded is maintained in a sanitary condition comparable to that of the food warehouse.

• Make sure that rail cars, trailers and trucks . . . are free of birds, rodents and insects or contamination from them,

. . . are free of odors, nails, splinters, oil, and grease,

. . . are free of accumulations of dirt or dunnage, and

. . . are in good repair and have no holes, cracks, or crevices that could provide entrances or harborages for pests.

8. *Follow-Up:*

8 Exercise programs of follow-up and control to ensure that your employees, consultants, and outside services are doing their jobs effectively.

REPRINT OF PART 128, TITLE 21 OF FEDERAL REGULATIONS

PART 128—HUMAN FOODS; CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURE, PROCESSING, OR HOLDING

Sec.

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128.10 Natural or unavoidable defects in food for human use that present no health hazard.

AUTHORITY: The provisions of this Part 128 issued under secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a) unless otherwise noted.

SOURCE: The provisions of this Part 128 appear at 34 FR 6977, Apr. 26, 1969, unless otherwise noted.

§ 128.1 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions shall also apply:

(a "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(b) "Plant" means the building or buildings or parts thereof, used for or in connection with the manufacturing, processing, packaging, labeling, or holding of human food.

(c) "Sanitize" means adequate treatment of surfaces by a process that is effective in destroying vegetative cells of pathogenic bacteria and in substantially reducing other micro-organisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.

§ 128.2 Current good manufacturing practice (sanitation).

The criteria in §§ 128.3 through 128.8 shall apply in determining whether the facilities, methods, practices, and controls used in the manufacture, processing, packing, or holding food are in conformance with or are operated or administered in conformity with good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions.

§ 128.3 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be free from conditions which may result in the contamination of food including, but not limited to, the following:

(1) Improperly stored equipment, litter, waste, refuse, and uncut weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, and other pests.

(2) Excessively dusty roads, yards, or parking lots that may constitute a source of contamination in areas where food is exposed.

(3) Inadequately drained areas that may contribute contamination to food products through seepage or foot-borne filth and by providing a breeding place for insects or micro-organisms.

If the plant grounds are bordered by grounds not under the operator's control of the kind described in subparagraphs (1) through (3) of this paragraph, care must be exercised in the plant by inspection, extermination, or other means to effect exclusion of pests, dirt, and other filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-processing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for sanitary operations and production of safe food. Floors, walls, and ceilings in the plant shall be of such construction as to be adequately cleanable and shall be kept clean and in good repair. Fixtures, ducts, and pipes shall not be so suspended over working areas that drip or condensate may contaminate foods, raw materials, or food-contact surfaces. Aisles or working spaces between equipment and between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contaminaton of food or food-contact surfaces with clothing or personal contact.

(2) Provide separation by partition, location, or other effective means for those operations which may cause contamination of food products with undesirable micro-organisms, chemicals, filth, or other extraneous material.

(3) Provide adequate lighting to hand-washing areas, dressing and locker rooms, and toilet rooms and to all areas where food or food ingredients are examined, processed, or stored and where equipment and utensils are cleaned. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.

(4) Provide adequate ventilation or control equipment to minimize odors and noxious fumes or vapors (including steam) in areas where they may contaminate food. Such ventilation or control equipment shall not create conditions that may contribute to food contamination by airborne contaminants.

(5) Provide, where necessary, effective screening or other protection against birds, animals, and vermin (including, but not limited to, insects and rodents)

§ 128.4 Equipment and utensils.

(a) *General.* All plant equipment and utensils should be (1) suitable for their intended use, (2) so designed and of such material and workmanship as to be adequately cleanable, and (3) properly maintained. The design, construction, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(b) *Use of polychlorinated biphenyls in food plants.* Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and non-flammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment and causing the contamination of certain foods. In addition, incidents

have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs). Since PCB's are toxic chemicals, the PCB contamination of food as a result of these accidents represents a hazard to human health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of food. The following special provisions are necessary to preclude accidental PCB contamination of food:

(1) New equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's.

(2) On or before September 4, 1973, the management of food plants shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling or processing food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not include PCB's.

(ii) Eliminate from the food plant any PCB-containing food-contact surfaces of equipment or utensils and any PCB-containing lubricants for equipment or machinery that is used for handling or processing food.

(iii) Eliminate from the food plant any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately de-

termined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(3) For the purposes of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.
[38 FR 18012, July 6, 1973]

§ 128.5 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to, the following:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts foods or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature and under pressure as needed shall be provided in all areas where the processing of food, the cleaning of equipment utensils, or containers, or employee sanitary facilities require.

(b) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(c) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment or utensils or create an insanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flood-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(d) *Toilet facilities.* Each plant shall provide its employees with adequate toilet and associated hand-washing facilities within the plant. Toilet rooms shall be furnished with toilet tissue. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and shall not open directly into areas where food is exposed to airborne contamination, except where alternate means have been taken to prevent such contamination (such as double doors, positive air-flow systems, etc.). Signs shall be posted directing employees to wash their hands with cleaning soap or detergents after using toilet.

(e) *Hand-washing facilities.* Adequate and convenient facilities for hand washing and, where appropriate, hand sanitizing shall be provided at each location in the plant where good sanitary practices require employees to wash or sanitize and dry their hands. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand-cleaning and sanitizing preparations, sanitary towel service or suitable drying devices, and, where appropriate, easily cleanable waste receptacles.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, prevent waste from becoming an

attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces, and water supplies.

§ 128.6 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the plant. These materials shall be identified and used only in such manner and under conditions as will be safe for their intended uses.

(b) *Animal and vermin control.* No animals or birds, other than those essential as raw material, shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues.

(c) *Sanitation of equipment and utensils.* All utensils and product-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Nonproduct-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to minimize accumulation of

dust, dirt, food particles, and other debris. Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, etc.) should be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that prevents contamination of food or food-contact surfaces. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and product-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruption during which such utensils and contact surfaces may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.

(d) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment and utensils with product-contact surfaces should be stored in such a location and manner that product-contact surfaces are protected from splash, dust, and other contamination.

§ 128.7 Processes and controls.

All operations in the receiving, inspecting, transporting, packaging, segregating, preparing, processing, and storing of food shall be conducted in accord with adequate sanitation principles. Overall sanitation of the plant shall be under the supervision of an individual assigned responsibility for this function. All reasonable precautions, including the following, shall be taken to assure that produc-

tion procedures do not contribute contamination such as filth, harmful chemicals, undesirable micro-organisms, or any other objectionable material to the processed product:

(a) Raw material and ingredients shall be inspected and segregated as necessary to assure that they are clean, wholesome, and fit for processing into human food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as required to remove soil or other contamination. Water used for washing, rinsing, or conveying of food products shall be of adequate quality, and water shall not be reused for washing, rinsing, or conveying products in a manner that may result in contamination of food products.

(b) Containers and carriers of raw ingredients should be inspected on receipt to assure that their condition has not contributed to the contamination or deterioration of the products.

(c) When ice is used in contact with food products, it shall be made from potable water and shall be used only if it has been manufactured in accordance with adequate standards and stored, transported, and handled in a sanitary manner.

(d) Food-processing areas and equipment used for processing human food should not be used to process non-human food-grade animal feed or inedible products unless there is no reasonable possibility for the contamination of the human food.

(e) Processing equipment shall be maintained in a sanitary condition through frequent cleaning including sanitization where indicated. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(f) All food processing, including packaging and storage, should be conducted under such conditions and controls as are necessary to minimize the potential for undesirable bacterial or other microbiological growth, toxin formation, or deterioration or contamination of the processed product or ingredients. This may require careful monitoring of such physical factors as time, temperature, humidity, pressure, flow-rate and such processing operations as freezing, dehydration, heat processing, and refrigeration to assure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of the processed products.

(g) Chemical, microbiological, or extraneous-material testing procedures shall be utilized where necessary to identify sanitation failures or food contamination, and all foods and ingredients that have become contaminated shall be rejected or treated or processed to eliminate the contamination where this may be properly accomplished.

(h) Packaging processes and materials shall not transmit contaminants or objectionable substances to the products, shall conform to any applicable food additive regulation (Part 121 of this chapter), and should provide adequate protection from contamination.

(i) Meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity should be utilized to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use. Records should be retained for a period of time that exceeds the shelf life of the product, except that they need not be retained more than 2 years.

(j) Storage and transportation of finished products should be under such conditions as will prevent contamination, including development of pathogenic or toxigenic micro-organisms, and will protect against undesirable deterioration of the product and the container.

§ 128.8 Personnel.

The plant management shall take all reasonable measures and precautions to assure the following:

(a) *Disease control.* No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person, or of disease being transmitted by such person to other individuals.

(b) *Cleanliness.* All persons, while working in direct contact with food preparation, food ingredients, or surfaces coming into contact therewith shall:

(1) Wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination of food products.

(2) Wash their hands thoroughly (and sanitize if necessary to prevent contamination by undesirable microorganism) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(3) Remove all insecure jewelry and, during periods where food is manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

(4) If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves should be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

(5) Wear hair nets, headbands, caps, or other effective hair restraints.

(6) Not store clothing or other personal belongings, eat food or drink beverages, or use tobacco in any form in

areas where food or food ingredients are expose or in areas used for washing equipment or utensils.

(7) Take any other necessary precautions to prevent contamination of foods with micro-organisms or foreign substances including, but not limited to perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education, or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food-handling techniques and food-protection principles and should be cognizant of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this Part 128 shall be clearly assigned to competent supervisory personnel.

§ 128.9 Exclusions.

The following operations are excluded from coverage under these general regulations, however, the Commissioner will issue special regulations when he believes it necessary to cover these excluded operations: Establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities, as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated or otherwise processed before being marketed to the consuming public.

§ 128.10 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing and/or processing practices, contain natural or unavoidable defects at lower levels that are not

hazardous to health. The Food and Drug Administration establishes maximum levels for such defects in foods produced under good manufacturing and/or processing practices and uses these levels for recommending regulatory actions.

(b) Defect action levels are established for products whenever it is necessary and feasible. Such levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse failure to observe either the requirement in section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this part that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection indicating such a violation renders the food unlawful, even though the amounts of natural or unavoidable defects are lower than the currently established action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food unlawful regardless of the defect level of the final food.

(e) Current action levels for natural and unavoidable defects in food for human use that present no health hazard are as follows. (Levels that have been adopted on a temporary basis prior to publication as a regulation may be obtained upon request at the Office of the Assistant Commissioner for Public Affairs, Food and Drug Administration, Room 15B-42, 5600 Fishers Lane, Rockville, Md. 20852.)

[38 F.R. 855, Jan. 5, 1973]

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

UNITED STATES OF AMERICA, *Petitioner*

v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR NATIONAL CANNERS ASSOCIATION, AMICUS CURIAE

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BRIEF FOR NATIONAL CANNERS ASSOCIATION, AMICUS CURIAE

Amicus submits this brief in support of the Respondent John R. Park. All parties have consented to its filing by a letter which has been presented to the Clerk of the Court pursuant to Rule 42(2).

INTEREST OF AMICUS

The National Canners Association is a nonprofit trade association of approximately six hundred members who have canning operations in forty-four states and the territories. Members of the Association pack

eighty to ninety percent of the entire national production of canned fruits, vegetables, juices, specialties, meat, and fish. Many aspects of its members' operations are subject to the requirements of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. §§ 301-392 (1970) ("the Act") and numerous comprehensive and technologically complicated regulations promulgated thereunder.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case involves the standard of individual criminal liability under the Act applicable to officers and employees of a corporation when violations of the Act and the extensive regulations under it occur in the course of the corporation's business.

Nearly all of the Association's members are corporations whose officers and employees may be directly affected by the articulation of that standard by this Court. The Association believes that any penal standard must protect both consumers and the rights of the officers and employees of its members. Since, under the Act, individuals may be sentenced to prison, [1] and upon a second conviction are branded as felons, [2] special considerations of justice and fair play must be taken into

[1] Section 303(a) of the Act, 21 U.S.C. § 333(a) (1970), provides:

"(a) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both."

[2] Section 303(b) of the Act, 21 U.S.C. § 333(b) (1970), provides:

"(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both."

account in defining that standard. Since these considerations are largely inapplicable to corporations, the Association's views expressed here are limited to the question of *individual* criminal liability.

Some thirty years ago, in *United States* v. *Dotterweich,* 320 U.S. 277 (1943), this Court held that an individual may be criminally liable for violations occurring in the course of a corporation's business if the "evidence produced at trial" shows the individual to have had "*a responsible share* in the furtherance of the transaction . . . ." 320 U.S. at 284 (emphasis added). At that time, the Court declined to define the class of employees having such a "responsible share" leaving the question for "submission . . . to the jury under appropriate guidance." *Id.* at 285.

Dotterweich involved a business where every management decision was made by a single individual acting directly as President and General Manager of a company with 26 employees at one location—three decades ago.[3] Since *Dotterweich,* the country's economy has evolved to a point where most of the goods covered by the Act are produced and distributed by corporations having chains of management command which necessarily function by delegation.

Many members of the Association have scores of packing plants and warehouses located throughout the nation and employing tens of thousands of employees. The management of these companies must necessarily function by delegating operational authority to sub-

[3] The factual situation in *Dotterweich* was reviewed by the Court of Appeals in this case and is summarized in the opinion below. United States v. Park, 499 F.2d 839, 841 n. 3 (4th Cir. 1974).

ordinates, in large part because of the physical separation between management—usually located at a corporate headquarters and the various processing operations—which must be located close to where different crops are grown.

Another factor which has lead to an increased need for delegation of operational authority, particularly with respect to compliance with the Act, has been the increasingly complex technical requirements imposed by the Food and Drug Administration ("FDA") under the Act since *Dotterweich*. These now fill six volumes of the Code of Federal Regulations.[4] In the case of the canning industry, regulations prescribe virtually every step of the canning process and are so technical and complex that they are literally unintelligible to those who lack complete technological training in these areas.

One need merely examine, as an example, the regulations applicable to "Thermally Processed Low-Acid Food Packaged in Hermetically Sealed Containers (21 C.F.R. Part 90 (1974); 21 C.F.R. Part 128b (1974)), to comprehend that only a specially trained individual can be expected to understand and implement those requirements. Indeed, the regulations specifically provide that the processing be conducted:

> "... under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in retort operations, processing systems operations, aseptic processing and packaging systems operations, and container closure inspections, and has been identified by that school as having satisfactorily completed the prescribed course of instruction." (21 C.F.R. § 128b.10).

[4] 21 C.F.R. §§ 1-1401.73 (1974).

Similarly detailed regulations, the interpretation of which may require medical, engineering, statistical and other forms of technical expertise, apply to the manufacturing and labeling of drugs, cosmetics and medical devices.[5] In some instances, these regulations are unrelated to any hazard to health and involve purely economic issues such as the proper type size and label format for stating net quantities of content in food packages.[6]

Since no company president can be expected to develop the requisite expertise in each of the fields needed

[5] *See, e.g.*, the current labeling requirements for certain medical diagnostic devices. 21 C.F.R. § 328.10 (1974). Among the most detailed of FDA's current labeling schemes, four pages of these regulations list required labeling information including:

> "[d]etails of calibration: Identify reference material. Describe preparation of reference sample(s), use of blanks, preparation of the standard curve, etc. The description of the range of calibration should include the highest and the lowest values measurable by the procedure.
>
> . . . .
>
> (11) Expected values: State the range(s) of expected values as obtained with the product from studies of various populations. Indicate how the range(s) was established and identify the population(s) on which it was established.
>
> (12) Specific performance characteristics: Include, as appropriate, information describing such things as accuracy, precision, specificity, and sensitivity. These shall be related to a generally accepted method using biological specimens from normal and abnormal populations. Include a statement summarizing the data upon which the specific performance characteristics are based."

21 C.F.R. § 328.10(b)(8)(v), (11) and (12) (1974).

These requirements alone require expertise in medicine, chemistry and statistics.

[6] *See, e.g.*, 21 C.F.R. § 1.8b (1974).

to interpret and implement compliance with the bulk of the FDA's present regulations, he must rely on technically trained subordinates. Top management is equally dependent on these qualified personnel for information as to any problems which might arise with respect to compliance. While a layman may be in a position to detect grossly insanitary conditions which are apparent to the naked eye, if he has the opportunity personally to scrutinize every canning plant or warehouse, he must rely on the assurances of others on such questions as whether sufficient samples are being tested to support a statistically sound quality control program.

It is against this background that trial courts today must consider and charge juries as to, under what circumstances, it is consistent with the intent of Congress and the purposes of the Act to impose absolute criminal sanctions, absent knowledge or intent, on chief executive officers and other management personnel for corporate violations, which may be based on a failure of a remote subordinate to conform to one of the massively detailed and technically complex regulations which the FDA routinely and increasingly promulgates under the Act today.[7]

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[7] Criminal prosecution of individuals under the Act are a frequent, if not everyday occurrence. A recent study of the agency's enforcement activities reveals that in 1973 approximately 90 criminal cases were forwarded to United States Attorneys for prosecution and in most, consistent with the FDA's policy, at least one responsible individual was charged. The United States Attorneys and the Department of Justice declined to prosecute only a very small percentage of these cases. *See* O'Keefe and Shapiro, *Personal Criminal Liability Under the Federal Food, Drug, and Cosmetic Act The Dotterweich Doctrine*, 30 Food Drug Cosm. L.J. 5, 27 (1975).

In the cases since *Dotterweich,* where individual defendants have denied having a "responsible share" in the transaction, the reported opinions of trial and appellate courts have generally justified a conviction with little more than a citation to or quotation from the rhetoric in *Dotterweich.*[8] In those cases it is clear that the individual defendants were intimately involved in and usually present on a day-to-day basis at the local site of the operations giving rise to the violations. Whatever may be said of the manner in which lower courts have dealt with that situation, as this case so clearly demonstrates, that approach is no longer adequate, in view of the changes in the regulated industries and the requirements under the Act since *Dotterweich.* One thing is clear. Some defined direction to lower courts is needed.

The difficulties inherent in applying a standard enunciated in a case involving a one man operation with 26 employees to the realities of today's disparate mass production have prompted some commentators to ask:

> "[w]ho has, and under what conditions does he have, 'a responsible share in the furtherance of

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[8] *See,* United States v. Cassaro, Inc., 443 F.2d 153 (1st Cir. 1971); Lelles v. United States, 241 F.2d 21 (9th Cir.), *cert. denied,* 353 U.S. 974 (1957); United States v. Hohensee, 243 F.2d 367 (3d Cir. 1957); United States v. H. Wool & Sons, Inc., 215 F.2d 95 (2d Cir. 1954); Golden Grain Macaroni Co. v. United States, 209 F.2d 166 (9th Cir. 1953); United States v. Kaadt, 171 F.2d 600 (7th Cir. 1948); United States v. Colosse Cheese and Butter Co., 133 F.Supp. 953 (N.D.N.Y. 1955); United States v. Diamond State Poultry Co., 125 F. Supp. 617 (D. Del. 1954). United States v. Parfait Powder Puff Co., 163 F.2d 1008 (7th Cir. 1947), *cert. denied,* 332 U.S. 851 (1948), cited by the Government in support of its view of the proper standard for individual liability (Govt. Brief at 25-26), is far wide of the mark. There was no individual defendant in the case.

the transaction which the statute outlaws'? When does he 'aid and abet' in the commission of the violative acts? When does he share 'responsibility in the business process resulting in unlawful distribution'?

"Sufficient time has elapsed since 1943, sufficient cases have been before the courts, and there is sufficient confusion on the point to warrant Supreme Court guidance. Hopefully, such guidance will be forthcoming from the Court, which has granted *certiorari* in the *Park* case."[9]

The Association believes that the opinion of the Court of Appeals below offers both a realistic and just approach to this question and presents this Court with an opportunity to give the lower courts the wise guidance which they will require vigorously yet fairly to apply the criminal sanctions of the Act to individuals.

The Court of Appeals held that in a prosecution of an individual under the Act "a finding of guilt must be predicated upon some wrongful action by [that individual]." 499 F.2d at 842. Recognizing that *Dotterweich* construed that Act as doing away with the usual requirement that the Government prove "awareness of wrongdoing", the Court stated that the "Government has confused the element of 'awareness of wrongdoing' with the element of 'wrongful action'; *Dotterweich* dispenses with the need to prove the first of those elements but not the second." *Id.* at 841. The Court of Appeals went on to hold that the individual's wrongful action may be "any of a host of . . . acts of commission or omission which would 'cause' the [violation]." *Id.* at 842. The Court of Appeals' choice of language also suggests that the act of commission or omission must,

[9] O'Keefe and Shapiro, *supra* note 7 at 24.

in some way, fall short of the standard of conduct which Congress sought to promote by the Act.

The standard enunciated by the Court of Appeals is consistent with the plain language of the statute, *Dotterweich,* subsequent cases in this Court relying or commenting upon *Dotterweich,* and most importantly, Congress' purpose in passing the Act. That standard will allow for vigorous enforcement of the Act without subjecting individuals to the *in terrorem* effect of a severe absolute penal sanction restrained only by the private judgment of those charged with its enforcement.

The language of the Act only prohibits the causing of certain acts and the failure to perform others.[10] Nothing in the statute remotely suggests that it is intended to criminalize the status of holding any particular corporate position or "standing" in any kind of "relationship" to a violation unless that relationship is defined in terms of an individual's conduct.

This was recognized in *Dotterweich,* where this Court made clear that an individual's "responsible relationship" to a situation, which might justify individual criminal liability, must necessarily be assessed in terms of those "settled doctrines of criminal law" employed to define those who, though not principal perpetrators of a crime, may be held liable as accessories, and in particular, as aiders and abettors. 320 U.S. at 284. Those doctrines require that an individual "associate himself with the venture . . . participate in it [and] . . . seek by his action to make it succeed." *United States* v. *Peoni,* 100 F.2d 401, 402 (2d Cir. 1938). The Court went on to stress that responsible relationships should

[10] 21 U.S.C. § 331.

be defined in terms of the "variety of conduct" in which the individual may have engaged. 320 U.S. at 285.

Subsequent to *Dotterweich*, this Court confirmed its original reliance on conduct in *Dotterweich* by contrasting *Dotterweich* with attempts to punish behavior that is "wholly passive". *Lambert* v. *California*, 355 U.S. 225, 228 (1957). More recently, this Court has "followed" *Dotterweich* in applying the criminal sanctions of § 1 of the Sherman Act to a corporate officer who "authorizes, orders, or helps perpetuate the crime." *United States* v. *Wise*, 370 U.S. 405, 416 (1962).

The Government's position on this issue is far from clear. Since it rested its case-in-chief after showing only that Park was Acme's president and that Acme's by-laws provided that he should "have general and active supervision of the affairs, business, offices, and employees of the company," (Govt. Brief at 6-7) it appears that the Government initially sought to rely solely on proof of Park's corporate position to establish his guilt. While in its Brief here, the Government now seems to concede that it must show some acts of commission or omission and prove "actual supervisory responsibility," (Govt. Brief at 25) the Government does not begin to define just what kind of acts it should be required to prove.

Despite the Government's protestations to the contrary, one is left with the clear impression that it seeks to rely on proof of an individual's corporate position buttressed, at most, by a showing of titular power and opportunity generally to influence the operations of the corporation which gave rise to the violation of the Act. That suggested standard, which is unrelated to an individual's actual conduct, knowledge or intent, bears no rational relationship to the purpose of the statute—which is clearly to influence behavior—not punish status.

In contrast to the Government's position, the standard enunciated by the Court of Appeals, requiring the Government to prove an act of commission or omission which "causes" a violation, is the traditional and time-tested judicial approach which focuses on conduct and reality.

In light of the clearly erroneous theory of the Government's case, upon which the trial court relied in instructing the jury, the Court of Appeals was not required to consider (if any of Park's acts of commission or omission caused a violation) whether the Government should have to show that Park's conduct fell below the standard which Congress sought to promote by the act. Nonetheless, the Court of Appeals' choice of the word "wrongful", as opposed to "causitive" suggests that it was sensitive to that issue.

The Federal Food, Drug, and Cosmetic Act is an example of a special form of legislation imposing criminal liability without regard to knowledge or intent for what have come to be known as public welfare offenses.[11] As this Court held in *United States* v. *Balint*, 258 U.S. 250 (1922), in such instances Congress may properly relieve the Government of its traditional burden of proving knowledge or intent in the interest of efficient enforcement. The purpose of such statutes is protection of the public, not punishment of an evil intent. The absence of consciousness of wrongdoing is

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[11] *See* Sayre, *Public Welfare Offenses*, 33 COLUM. L. REV. 55 (1933).

considered irrelevant. These statutes are designed to protect the public by "stimulat[ing] proper care." *Id.* at 253. That principle, enunciated in *Balint* and relied on in *Dotterweich,* finds limitations in its rationale. If an individual is to be stimulated to take proper care by the threat of criminal sanction for his failure to do so, he must be aware that some problem exists and that, therefore, there is some need to take special precautions or corrective measures. In short, if an individual could not have reasonably foreseen that the consequences of an act or omission might be a violation of the Act, he should not be held criminally liable. In the language of *Dotterweich,* he did not have "the opportunity of informing [himself] of the existence of the conditions" which might result in violations. 320 U.S. at 385.

The Government appears to acknowledge this limitation on *Dotterweich* when it states that individuals:

> "who were totally unaware of any problem and could not have been expected to be aware of it in the *reasonable* exercise of their duties are not the subject of criminal action." Govt. Brief at 31. (emphasis added).

Just as there is no purpose in punishing individuals for unforeseeable consequences of their acts or omission, once a person has taken every reasonable precaution to prevent violations of the Act, at that point, threat of criminal sanction, however severe, cannot stimulate greater care.

This was recognized in *Morissette* v. *United States,* 342 U.S. 246 (1952), where the Court suggested that public welfare statutes hold individuals to only a "reasonable" standard, and subsequently, in *United*

States v. *Wiesenfeld Warehouse Co.,* 376 U.S. 86 (1964), when this Court noted that the Act's criminal sanctions were not intended to apply to those who are "'powerless' to protect against" the violation. 376 U.S. at 91. Consistent with this view, the legislative history of the 1938 Act suggests that Congress intended to punish only those who cause violations through "inadvertence, carelessness or negligence," S. Rep. No. 493, 73d Cong. 2d Sess. 20 (1934), and nothing in the subsequent legislative history of amendments and proposed amendments to the Act suggests to the contrary.

In considering the impact of affirming the Court of Appeals, this Court should keep two principal issues in mind: the effect that the Court of Appeals' standard would have on enforcement of the Act and the effect that adoption of the Government's position would have on the rights of individuals.

The Government would have this court believe that adoption of the standard enunciated by the Court of Appeals would leave enforcement of the Act in a shambles. Nothing could be further from the truth. Criminal prosecutions of individuals is but one of the arsenal of sanctions effectively available to the FDA to secure compliance with the Act. The FDA has the statutory power to seize goods that violate the Act wherever they may be found and where there is a threat to the public health; the statute authorizes seizures which literally result in destruction of the offending goods.

The FDA can also proceed by way of injunction against both individuals and corporations. This can effectively close down an entire food processing plant and may in effect put it out of business for good. In the case of canned foods, special statutory authority

allows the FDA to require a canner to conduct his operations pursuant to a permit spelling out, in detail, the precautions which must be taken to protect the public. Finally the FDA is authorized by statute to fully and immediately publicize violations involving hazards to the public health or gross frauds that publicly cannot only protect the public but may also put the violator permanently out of business.

In addition to its statutory authority, the *threat* of statutory action allows the FDA to pressure manufacturers into engaging in "voluntary" recalls. These are, in effect, self-imposed seizures and injunctions. In fact, all of the problems which the FDA has raised with the Court of Appeals' standard are straw-men and do not present any practical hurdles to the Act's vigorous enforcement. This is clearly indicated by the fact that the FDA's current enforcement policies and procedures are entirely consistent with the Court of Appeals' standard.

While the impact of the Court of Appeals' standard on the enforcement of the Act is minimal, were this Court to embrace the Government's position, it would create a situation unparalleled in this country's judicial history. Because of the inevitability of technical violations, which can be made out on the basis of failure to conform to one of the FDA's comprehensive, technically complex and sometimes unclear regulations, the Government standard would place every executive of a firm making or dealing in products regulated under the Act, in a position where his civil liberties existed "on the basis solely of the private judgment of his prosecutors." [12]

[12] Hart, *The Aims of the Criminal Law*, 23 LAW & CONTEMP. PROB. 401, 424 (1958).

While no suggestion is made that the FDA seeks this awesome power to abuse it, even recent history teaches that this country must remain a government of laws and not men. As time worn as the phrase may be, Lord Acton was correct in admonishing that "absolute power corrupts absolutely." [13]

Since the trial court's instructions to the jury clearly adopted the Government's extreme and unwarranted view of *Dotterweich* and thereby created a substantial probability that the jury convicted Park solely on the basis of his corporate position, without regard to his conduct, the Court of Appeals' must be affirmed.

ARGUMENT

I. The Court of Appeals Correctly Interpreted the Act and Dotterweich as Requiring the Government, in a Criminal Prosecution of an Individual, To Prove an Act of Commission or Omission by the Defendant.

In the decision below, the Court of Appeals correctly held that the Act, as interpreted by this Court in *Dotterweich,* requires proof of wrongful action by a corporate officer or employee to establish a violation of the Act by that person:

> "[t]he jury should be instructed that a finding of guilt must be predicated upon some wrongful action by [the individual defendant]. That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' [the violation]." 499 F.2d at 842 (footnotes omitted).

This conclusion is consistent with the plain language of the statute. Section 301, which is subtitled "Pro-

[13] Letter to Bishop Mandell Creighton, 1887.

hibited Acts," begins: "[t]he following acts and the causing thereof are hereby prohibited . . . ." The "acts" enumerated thereafter include the "failure" to do certain things. Thus, the term "acts" encompasses acts of omission as well as acts of commission. However, there is no language in Section 301 which even remotely suggests that criminal liability determined without regard for intent or knowledge can be predicated merely on an individual's titular position in a business organization.

The Court of Appeals' conclusion is also consistent with settled doctrines of criminal law. It is a fundamental tenet that conviction of a crime requires proof of both the *actus rea* and the *mens rea*.[14] A limited exception exists for what have come to be called "public welfare offenses."[15] In these cases, it has been held that the legislature may properly eliminate the usual requirement that the Government prove the defendant's intent or knowledge (*mens rea*) because the purpose of such statutes is to protect the public, not to punish an evil doer.[16] Since intent is considered irrelevant, the requirement that the Government prove intent is eliminated in order to ease the burden of securing convictions and thereby increase the efficiency of enforcement.

This concept, which is discussed more fully below,[17] appears to have become established as a limited exception to the general concepts of criminal jurisprudence.

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[14] 4 W. BLACKSTONE, COMMENTARIES *21.

[15] *See* Sayre, *supra* n. 11.

[16] United States v. Balint, 258 U.S. 250 (1922).

[17] See pp. 24-27 *infra*.

It was against this background that this Court in *Dotterweich* construed the Act as eliminating the requirement that the Government prove intent or knowledge in criminal prosecutions thereunder. As recognized by the Court of Appeals, however, while *Dotterweich* did away with the need to prove "awareness of wrongdoing," it did not dispense with the need to prove "wrongful action." 499 F.2d at 842.

In *Dotterweich*, the Court stated that individual criminal liability under the Act reaches "all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor." 320 U.S. at 284. The Court went on to clarify this reference to "settled doctrines," stating:

> "[t]o speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty." *Id.*

A brief review of the "settled doctrines" to which the Court referred, and in particular the standards for determining those liable as aiders and abettors, dispels any doubt that the Government must, in each case, prove an act of commission or omission. In *United States* v. *Peoni*, 100 F.2d 401 (2d Cir. 1938), Judge Learned Hand considered the circumstances under which an individual, while not the principal perpetrator of an offense, could nonetheless be held criminally liable as an accessory, particularly as one who "aids" or "abets." Noting that the doctrine was established by the beginning of the Fourteenth Century, Judge Hand reviewed its development to modern times and concluded:

> "[i]t will be observed that all these definitions . . . demand that he in some sort associate himself with

> the venture, that he participate in it as in something that he wishes to bring about, that he seek by his action to make it succeed." 100 F.2d at 402.[18]

Dotterweich did not construe the Act as eliminating the requirement that the Government prove some act of commission or omission by the individual defendant. On the contrary, the Court there declined,

> "[t]o attempt a formula embracing the variety of *conduct* whereby persons may responsibly contribute in furthering a transaction forbidden by [the] Act . . . ." 320 U.S. at 285 (emphasis added.)

That *Dotterweich* did not so construe the Act has also been recognized by several later cases in this Court which have relied upon or considered *Dotterweich*. In *Lambert* v. *California*, 355 U.S. 225 (1957), this Court struck down, as a violation of the due process clause of the fourteenth amendment, the conviction of an individual under a provision of the Los Angeles municipal code which made it a crime for a person convicted of a felony to be in Los Angeles for a period of more than five days without registering with the chief of police. The prosecution had proved only that the individual was a convicted felon and a long time resident of Los Angeles and that she had not registered. It was established that she had "no actual knowledge of the requirement that she register . . . [and] . . . no showing [was] made of the probability of such knowledge." 355 U.S. at 227. The Court distinguished this situation from the circumstances justifying a conviction under *Dotterweich* stating:

[18] This language was quoted with approval in Nye & Nissen v. United States, 336 U.S. 613, 619 (1949).

> "we deal here with conduct that is wholly passive—mere failure to register. It is unlike the commission of acts, or the failure to act under circumstances that should alert the doer to the consequences of his deed . . . . *United States* v. *Dotterweich*, 320 U.S. 277, 284." 355 U.S. at 228.

In *United States* v. *Wise*, 370 U.S. 405 (1962), where the issue was whether a corporate officer could be held individually criminally liable under § 1 of the Sherman Act, 15 U.S.C. § 1 (1970), for actions taken solely in a representative capacity, the Court stated:

> "[f]ollowing *Dotterweich*, we construe § 1 of the Sherman Act in its common-sense meaning to apply to all officers who have a responsible share in the proscribed transaction. Cf. *Carolene Products Co.* v. *United States*, 323 U.S. 18, 21.
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> . . . we hold that a corporate officer is subject to prosecution under § 1 of the Sherman Act whenever he . . . participates in effecting the illegal contract, combination, or conspiracy—be he one who authorizes, orders, or helps perpetrate the crime—regardless of whether he is acting in a representative capacity." 370 U.S. at 409-16.

The Government's present position on this issue is far from clear. Initially, it asks the Court to interpret the Act as eliminating the need to prove "*particular* acts of omission or commission" (Govt. Brief at 2) (emphasis added). There would be no purpose in adding the qualifying phrase "particular" if the Government did not concede that it is required to prove some acts of omission or commission. Yet the Government never squarely addresses the issue of what showing is enough.

At one point the Government argues that "affirmative 'wrongful action' by the accused is not required" (Govt. Brief at 24); but this is conceded by all. The Court of Appeals plainly stated that the necessary "wrongful action" could be "any of a host of . . . acts of . . . omission." 499 F.2d at 842. The Government also admits that it "must offer proof of *actual* supervisory responsibility relating to the prohibited conditions" (Govt. Brief at 25) (emphasis added), and disclaims any intention of attempting to base a conviction solely on Mr. Park's position as president of the corporation.

Yet at trial, the only evidence introduced in the Government's case-in-chief tending to show that Park had *any* supervisory responsibility for sanitation was evidence that Park was Acme's president and the testimony of Acme's General Counsel that the corporation's by-laws provided that as president, Park "shall, subject to the board of directors, have general and active supervision of the affairs, business, offices, and employees of the company." (Govt. Brief at 6-7).

It would be difficult to find a chief executive officer of any business corporation whose duties were not described by the company's by-laws in substantially similar terms. If, in the Government's view, proof that the defendant is the corporation's chief executive officer is synonomous with proof of actual supervisory responsibility—the Government's offer to prove actual supervisory responsibility and its denial that it seeks to rely merely on titular responsibility is disingenuous.

In contrast to the Government's inability to articulate, in a meaningful way, the nature of any act of commission or omission which it must prove to obtain conviction of an individual, the Court of Appeals has formulated a standard which is not only clear but also has the advantage of being a traditional judicial standard, familiar to both judges and juries. That standard is causation. It presents the trier of fact with a very practical question: was the violation caused by, in whole or in part, an act of commission or omission by the defendant? Judges and juries have for centuries dealt with essentially this question in thousands of cases. There is no reason to believe that the standard should now prove unequal to the task.

It should also be recognized that judges and juries are also experienced with causation which may be indirect or contributory. Contrary to suggestions in the Government's brief (Govt. Brief at 38), the Court of Appeals did not suggest that the defendant's act of commission or omission must be related to the contamination of a specific lot of food or a specific shipment of a misbranded drug. It is sufficient to show that the defendant's act resulted in a situation, the natural consequence of which was the particular violation alleged. If the Government's real concern about proof of "particular acts of omission or commission," is that they will always have to prove direct causation, then the differences between the Government's position and the standard announced by the Court of Appeals is insignificant.

If on the other hand, the Government's true posture is that it need not prove *any* act of commission or omission by the individual, but rather only a "responsible relation" to the violation, assessed solely in light of the individual's position within the corporation, this is not only contrary to the language of the Act and

Dotterweich, it bears no rational relation to the purpose of the statute.

The principal purpose of criminal prohibitions, whether "public welfare offenses", common law or statutory offenses, is to influence conduct—deter individuals from doing certain acts and stimulating them to do others. If one refrains from the prohibited and accomplishes that which is required, one cannot properly be punished. Criminal liability, unrelated to acts of commission or omission, cannot deter individuals from doing certain acts or stimulate them to do others.

There is nothing illegal about being president of a supermarket chain. Nor is there anything *per se* illegal about being president of a supermarket chain which, as a corporation engaged in a generally lawful business, nonetheless violates the Act. For the criminal law was never intended to affect mere status. Mere status is neither good nor bad in the abstract. Therefore, a standard which imposes criminal liability on individuals on the basis of mere status, *wholly without regard to conduct,* bears no rational relation to the purpose of the statute. Certainly that standard should not be declared to be the law in the absence of the clearest expression by Congress of an intent to legislate in so novel a fashion.

II. Criminal Penalties Should Not Be Inflicted on Individuals Who Have Met the Standards of Conduct Which Congress Sought To Promote by the Act.

The Court of Appeals held that, in addition to proving an act of commission or omission by an individual, the Government must also prove that the act was "wrongful." 499 F.2d at 842. In a footnote, the Court of Appeals defined "wrongful action" as acts

which "cause" a violation. *Id.* at 841. The use of the term "wrongful" in the text indicates, however, that the Court of Appeals was sensitive to the fact that there should be *some* showing that the individual's behavior fell short of the standard of conduct which Congress sought to promote by the Act.

There is no rational basis for punishing an individual whose conduct meets that standard. To do so would "so outrage the feelings of the community as to nullify [the Act's] enforcement."[19] It is not clear that the Government disagrees with the Court of Appeals' suggestion on this point. Sufficient confusion exists, however, and the point is important enough to merit this Courts' consideration and resolution of the issue.

At the beginning of this century, Congress sought to protect the public from impure or dangerous foods and drugs by enacting several statutes making distribution of these articles in interstate commerce a criminal offense. Among these statutes were the original Food and Drugs Act of 1906[20] and the Narcotics Act of 1914.[21] Neither statute contained explicit requirements that violations be committed "knowingly" or "willfully."

United States v. *Balint,* 258 U.S. 250 (1922), the seminal case in the area, involved a prosecution under the Narcotic Act of 1914 for the unlawful distribution of narcotic drugs. The defendants objected that the indictment failed to allege that they knew that the

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[19] Sayre, *supra* note 11, at 56.

[20] Federal Food and Drugs Act of June 30, 1906, ch. 3915, 34 Stat. 768.

[21] Narcotic Act of December 17, 1914, ch. 1, 38 Stat. 785.

drugs were narcotics. The Court found the indictment adequate, stating:

> "[w]hile the general rule at common law was that the *scienter* was a necessary element in the indictment and proof of every crime, and this was followed in regard to statutory crimes even where the statutory definition did not in terms include it (*Reg.* v. *Sleep,* 8 Cox C.C. 472), there has been a modification of this view in respect to prosecutions under statutes the purpose of which would be obstructed by such a requirement. It is a question of legislative intent to be construed by the court." 258 U.S. at 251-52.

The Court held that Congress had eliminated the requirement that the Government prove knowledge or intent, observing "the emphasis of the statute is evidently upon achievement of some social betterment rather than the punishment of the crimes . . . ." *Id.* The Court concluded:

> "where one deals with others and his mere negligence may be dangerous to them, as in selling diseased food or poison, the policy of the law may, in order to stimulate proper care, require the punishment of the negligent person though he be ignorant of the noxious character of what he sells. *Hobbs* v. *Winchester Corporation,* [1910] 2 K.B. 471, 483.
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> . . . Doubtless considerations as to the opportunity of the seller to find out the fact and the difficulty of proof of knowledge contributed to this conclusion." 258 U.S. at 252-54.

But the principle enunciated in *Balint,* and upon which the *Dotterweich* decision rests, finds its limitations in its rationale. If the purpose of criminal sanctions is to "stimulate proper care," there is no basis for applying them to those who neither know nor should know that any special precautions or corrective measures are called for. Individuals cannot be "stimulated" by the threat of criminal sanctions of which they are unaware. An individual's awareness of a problem is a necessary prerequisite of his awareness of the potential criminal consequences of his conduct in relationship to that problem. In short, individuals should be held criminally liable only if the consequences of their conduct were reasonably foreseeable. If they could not have reasonably foreseen the violation, in the language of *Dotterweich,* they did not have "the opportunity of informing themselves of the existence of [the] conditions" which might result in that violation. 320 U.S. at 285.

The Government acknowledges the relevance of foreseeability:

> "Officials . . . who were totally unaware of any problem and could not have been expected to be aware of it in the *reasonable* exercise of their corporate duties, are not the subject of criminal action." Govt. Brief at 31 (emphasis added).

To similar effect is this Court's opinion in *Lambert* v. *California,* 355 U.S. 225 (1957), which indicated that *Dotterweich* was limited to situations involving

> "the commission of acts, or the *failure to act under circumstances that should alert the doer to the consequences of his deed.*" 355 U.S. at 228 (emphasis added).

The Court of Appeals for the District of Columbia Circuit has also interpreted *Dotterweich* as requiring

foreseeability. In *Belsinger* v. *District of Columbia,* 436 F.2d 214 (D.C. Cir. 1970), the court overturned an action by the Electrical Board of the District of Columbia suspending the master electrician specialist license of an individual. The individual was the president of a company, the employees of which had made electrical connections for gasoline stations without obtaining required permits. The court stated:

> "[i]f the Board is seeking to penalize appellant Belsinger based on his position as president of the Maintenance Corporation, it must prove that he either knew or should have known of the forbidden and dangerous work being done by employees of the Maintenance Corporation, and took no action to stop it." 436 F.2d at 220 (citing *Dotterweich).*

Just as there is no purpose in punishing individuals for unforeseeable consequences of their acts or omissions, those who are aware of potential problems and do those things which can reasonably be expected to prevent them, should not be the subject of criminal punishment, even if an occasional violation occurs despite their efforts. For once a person has taken reasonable precautions to prevent violations of the Act, at that point, threat of criminal sanction, however severe, cannot stimulate greater care.

This was recognized, at least implicitly, in *Morissette* v. *United States,* 342 U.S. 246 (1952), in which this Court observed that in public welfare offenses, where the requirement that the Government prove intent or knowledge is eliminated,

> "[t]he accused, if he does not will the violation, usually is in a position to prevent it with no more care than society might reasonably expect and no more exertion than it might reasonably exact from one who assumed his responsibilities." 342 U.S. at 256.

Subsequently, in *United States* v. *Wiesenfeld Warehouse Co.,* 376 U.S. 86 (1964), this Court applied that limitation to the Act, noting that the Act's criminal sanctions were not intended to apply to those who are "'powerless' to protect against" the violation. 376 U.S. at 91.

While the Government's Brief recognizes that criminal liability can attach only to those officers and employees who have the power to prevent violations (Govt. Brief at 14, 22), there is a suggestion that the power need only be titular and theoretical and that if a violation occurs, individuals with such theoretical power should be subject to criminal penalties, including imprisonment, despite the fact that they may have taken every reasonable precaution to prevent the violation. Not only does this position bear no rational relation to the purpose of the statute, the legislative history of the Act does not support the conclusion that Congress intended this result.

There is nothing in the legislative history of the 1938 Act which suggests that Congress intended to create standards of individual criminal liability which would punish persons who had taken reasonable precautions to comply with the Act. Indeed the Senate Report on S. 2800, one of the bills from which the 1938 Act evolved, suggests the opposite conclusion.[22] In commenting on a provision which increased penalties for violations committed "with the intent to defraud or mislead," the Report contrasted such "willful" viola-

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[22] S. Rep. No. 493, 73d Cong. 2d Sess. 20 (1934).

tions with those which occur "through inadvertence, carelessness, or negligence." Each of these three phrases connotes a *failure* to exercise proper care and strongly suggest that Congress did not envision the criminal prosecution of individuals who take proper care.[23]

The legislative history of the subsequent amendments and proposed amendments to the Act cited by the Government (Govt. Brief at 29-30) similarly does not support the view that Congress intended to endorse a standard of criminal liability which would punish individuals who have exercised proper care. When, in 1948, Congress considered amendments to the Food, Drug, and Cosmetic Act, in the form of S. 1190 and H.R. 4071, its principal concern was the effect of the decision in *United States* v. *Phelps-Dodge Mercantile Co.*, 157 F.2d 453 (9th Cir. 1946), *cert. denied*, 330 U.S. 818 (1947), which narrowly limited the application of the adulteration provisions of the Act. The issue of individual criminal liability was not even considered in the House.[24] The Senate passed the so-called Moore Amendment,[25] which was added from the floor [26]

[23] Webster's New International Dictionary (2d ed. unabridged 1954) defines inadvertence as:

> "1. The fact or action of being inadvertent; lack of heedfulness or attentiveness; inattention. 2. An effect of inattention; a result of carelessness; an oversight, mistake, or fault from negligence. Syn.—Heedlessness, carelessness, thoughtlessness. See NEGLIGENCE. Ant.—Care, diligence, assiduity, carefulness."

[24] *Hearings on H.R. 3128 and H.R. 3147 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 80th Cong., 1st Sess. (1947); 94 CONG. REC. 134-137 (1948).

[25] 94 CONG. REC. 8239 (1948).

[26] 94 CONG. REC. 6760-61 (1948).

and which would have required a showing of "willfulness' or "gross negligence" prior to a criminal prosecution of *any* "person". *Id.* While this amendment was dropped in conference, the Conference Report makes no mention of the reason for its deletion.[27]

Even if one accepts the Government's characterization of these events as a Congressional "refusal" to adopt the standard of the Moore Amendment (Govt. Brief at 30), that is irrelevant. Refusing to require the Government to prove "willfulness" or "gross negligence" in prosecutions of individuals *and* corporations is far different from authorizing conviction of an individual in the face of a showing that that individual has done those things reasonably within his power to prevent violations of the Act.

III. Requiring that a Conviction of an Individual Be Based on His Wrongful Action Will Not Interfere with Effective Enforcement of the Act.

A requirement that an individual's criminal conviction rest on proof of some act of commission or omission by that individual will not hinder effective enforcement of the Act. Nor will a requirement that the conduct must fall below the standards which Congress sought to promote by the Act. The problems which the Government suggests would result from observing these requirements are more imagined than real, and both requirements are entirely consistent with the Government's announced and actual enforcement policies.

A. THE DECISION OF THE COURT OF APPEALS CONCERNS ONLY ONE OF THE FDA'S SEVERAL ENFORCEMENT TOOLS.

In addition to criminal prosecution of corporations and corporate employees, the Act provides both judi-

[27] H. R. REP. No. 2400, 80th Cong. 2d Sess. (1948).

cial and non-judicial sanctions. Moreover, the FDA has developed highly effective non-statutory remedies against the distribution of illegal articles. Under Section 304 of the Act, goods that the FDA believes violate any of the statutory or regulatory standards may be seized while held for introduction into commerce, while in commerce, or while held for sale after shipment in commerce, regardless of the number of transfers of ownership that have taken place.[28] Where goods are dangerous to health, the FDA is authorized under Section 304(a)(1)(B), to make multiple seizures wherever the goods may be found.[29] This remedy can bar the shipment of a warehouse of goods assertedly underprocessed, or can sweep from supermarket shelves a product using an unapproved additive.

The FDA also has two forms of injunctive relief available to it. Under Section 302 of the Act, it can move in court to enjoin corporations and individuals from violating any of the prohibited acts, including the delivery for introduction of any goods that are misbranded or adulterated.[30] This authority can effectively close down a food processing operation, and in the case of one dependent upon seasonal harvesting of agricultural raw materials, could be in fact ruinous. In the case of canned food, the FDA has exercised its special statutory authority to monitor the adequacy of the crucial thermal processing system.[31] Under Section 404 of the Act, deviations from required processing steps can result in an administrative order barring the firm from

[28] 21 U.S.C. § 334 (1970).

[29] 21 U.S.C. § 334(a) (1) (B) (1970).

[30] 21 U.S.C. § 332 (a) (1970).

[31] 21 U.S.C. § 344 (1970); 21 C.F.R. Part 90 (1974).

shipping goods in commerce until, under a "permit", the FDA determines that adequate processing is being done.

The FDA has the final statutory remedy under Section 705 of publicity.[32] The agency is permitted to publicize through every type of media instances where health hazards or gross fraud may exist. The effects of publicity can ruin trademarks and devastate seasonal sales.

In addition to these explicit statutory remedies, the FDA has developed a number of non-statutory but often equally effective procedures for protecting the public from illegal articles. The foremost of these is the "recall," which, under the FDA, has been carefully stratified according to the severity of the problem, the scope of merchandising outlets to be canvassed for the goods, and the degree of publicity to be used. Under the threat of the full panoply of judicial sanctions, firms thus use their own resources in what amount to self-imposed injunctions and multiple seizures.

All of the foregoing sanctions apply regardless of the potential or actual imposition of criminal sanctions. They apply completely to the violative goods and not to individuals. They apply, however, with often devastating economic consequences—to particular brands of products, to particular lines of products, and indeed at times even to companies as a whole. It is against this panoply of enforcement powers that FDA's need for individual criminal prosecutions, and their impact on the individuals involved, must be considered.

[32] 21 U.S.C. § 375 (b) (1970).

B. A STANDARD BASED ON CONDUCT WILL NOT PLACE SERIOUS BURDENS ON GOVERNMENT PROSECUTORS.

The Government exaggerates the burden which would be placed on prosecutors by a standard requiring proof of an act of commission or omission by the individual. As noted above, the Government's suggestion that it would be required to show an "affirmative 'wrongful action' by the accused" (Govt. Brief at 24) is negated by the Court of Appeals' statement that it would be sufficient to show "any of a host of . . . acts of commission or omission which would 'cause' the [violations]." 499 F.2d at 842. Similarly, the Government's complaint that the Court of Appeals' standard would require proof, in food cases, of an act of commission or omission directly related to a "particular lot of flour or breakfast cereal" is unwarranted. Govt. Brief at 38. Nothing in the Court of Appeals' opinion suggests that in food adulteration cases growing out of insanitary storage conditions, the Government would have to show more than the foreseeability of the insanitary conditions by the individual and his failure to take reasonable preventive or corrective measures which were within his power to institute.

C. A STANDARD BASED ON CONDUCT WILL NOT PERMIT CORPORATE OFFICERS TO "ISOLATE" THEMSELVES FROM CRIMINAL LIABILITY.

Contrary to the Government's assertion, a standard of individual criminal liability based on the individual's conduct would not encourage corporate officers and employees to "isolate" themselves from possible liability. As a practical matter, those situations which may give rise to violations of the Act by the corporation are so inexorably woven through the fabric of the entire business enterprise that corporate officers and other management personnel could not "isolate" themselves from potential violations of the Act without so isolating themselves from the general conduct of the corporation's business as to be unable to function effectively in their executive positions.

Even if individuals in top management were to attempt to carve out responsibility for compliance with the Act and delegate it away, in the case of intentionally fraudulent or flagrant violations, they will almost certainly nonetheless have actual knowledge of the violation. If they have purposefully isolated themselves from even knowledge of intentionally fraudulent and flagrant violations, that act alone could be sufficient to support the imposition of individual criminal liability for the corporate violation since the very act of "isolation" is itself suggestive of the foreseeability of the violation.

D. THE FDA'S ANNOUNCED AND ACTUAL ENFORCEMENT POLICY IS DIRECTED ONLY AT THOSE INDIVIDUAL CORPORATE OFFICERS AND EMPLOYEES WHOSE ACTS OF COMMISSION OR OMISSION CAUSE VIOLATIONS OF THE ACT AND FALL SHORT OF THE STANDARD OF CONDUCT WHICH CONGRESS SOUGHT TO PROMOTE BY THE ACT.

In its brief, the Government declares that it is,

> "FDA policy to limit prosecutions to continuing violations, violations of an obvious or flagrant nature, and intentionally false or fraudulent violations." Govt. Brief at 16.

A recent study of the agency's actual enforcement procedures confirms that they conform to this policy.[33] In particular, the study found that, except in extraordinary cases, "FDA policy provides for a 'warning' to potential defendants and an opportunity to comply vol-

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[33] O'Keefe and Shapiro, *supra* note 7.

untarily." *Id.* at 25. Review of a sample of unreported cases showed that,

> "[i]n every case some form of warning and follow-up inspection was provided . . . . Indeed, given the warnings and subsequent acts of omission in a number of instances, it could be said there were both awareness of wrongdoing and wrongful action on the part of individuals prosecuted in these cases." *Id.* at 30.

Thus the Government's enforcement policies are consistent with a requirement that it prove an act of commission or omission by the individual. Barring the exceptional circumstance where an employee engages in a frolic of his own, if a corporate violation is intentionally fraudulent or flagrant, the Government should have little difficulty in convincing a jury that top corporate officials either knew of the violation, or at least failed to take reasonable precautions to prevent the violation.

IV. It Is "An Arrogant Assertion that It Is Proper To Visit the Moral Condemnation of the Community Upon One of Its Members on the Basis Solely of the Private Judgment of His Prosecutors." [34]

The Government argues that there is no difficulty in reading into the Act a Congressional intent to subject individuals to a standard of criminal liability, where guilt turns on the defendant's corporate position, without regard to conduct, because the individual's rights will be protected by "the good sense of prosecutors." Govt. Brief at 31. While prosecutorial discretion is recognized as a necessary if not always heralded

[34] Hart, *supra* note 12, at 424.

aspect of our criminal system, as noted by Professor Hart, the implications of the Government's suggestion are staggering.

Given the ease with which the FDA can discover at least one violation of the Act by a company engaged in the manufacture or distribution of foods, drugs, cosmetics, or medical devices, regardless of the care the president of the corporation may have taken to prevent the violation—under the standard urged by the Government, there is nothing which the president can do to avoid conviction, a fine and possible imprisonment, beyond trusting in the goodwill of the FDA. The concept of individual civil liberties existing at the discretion of any executive agency of government is repugnant to this country's entire judicial and political heritage. While no suggestion is made that the FDA or the Department of Justice seek this power to abuse it, where the harsh operation of the law is realistically and admittedly stayed only by the discretion of those charged with its enforcement, the rights of individuals have no real substance.

V. The Jury Instruction Given at Park's Trial Improperly Focused Almost Entirely on Park's Corporate Position and Probably Led the Jury to Convict Park Solely on that Basis.

Viewed in the light of the requirement of the Act, that the conviction of an individual must rest on proof of his wrongful conduct, as properly enunciated by the Court of Appeals, the trial court's instruction to the jury was so prejudicially confusing as to require that Park's conviction be reversed. The thrust of the instruction was that Park could be found guilty "by virtue of his position in the company." App. 62.[35] Under

[35] References designated "App." are to the printed Appendix filed by the Government in this case on December 26, 1974.

the instruction, the jury could have convicted Park even though it believed that he was guilty of neither acts of commission nor omission related to the corporate violations.

Comparison of the instruction given at Park's trial with the instruction given in *Dotterweich* does not save it. In *Dotterweich,* no attempt was made to equate Dotterweich's guilt or innocence with his position in the company. Rather the court posed the issue in terms of "[w]as he responsible for the shipment . . . [i]n other words . . . were [they] made under his supervision by him as 'General Manager' " [36]

One cannot read the instruction in *Dotterweich* and escape the conclusion that the trial court clearly indicated to the jury that to convict it had to find that the defendant personally participated in the violation, at least to the extent of authorizing his agents to do the acts on his behalf.

The instruction at Park's trial clearly focused the jury's attention on Park's corporate status. In *Dotterweich,* the court only cautioned the jury that the defendant need not have "personally and physically made the shipment himself," and no suggestion was made that Dotterweich need not have participated in the violation. In contrast, in Park's case, the trial court on *two* occasions told the jury that "he need not have personally participated in the situation." App. 62. The only additional guidance which the trial court gave, other than telling the jury that they were not *compelled* to convict on the basis of Park's title alone, was that Park had to have had a "responsible relation to the

[36] The text of the jury instruction given in *Dotterweich* appears as a footnote in the Government's Brief at page 24.

situation." *Id.* There was no further explanation of what constituted such a "responsible relation" and the trial judge specifically denied a request for further definition. App. 62-63. In the context of a charge dominated in the beginning by repeated references to the defendant's corporate position and the irrelevance of personal participation, the jury could easily have equated the issue of "responsible relation" with the fact of Park's corporate position and not as a direction to determine guilt or innocence in terms of Park's conduct. As the Court of Appeals found:

> ". . . the court told the jury that Park would be guilty if it were shown that he 'had a position of authority and responsibility in the situation out of which these charges arose.' This instruction, taken in combination with the other parts of the charge related above, might well have left the jury with the erroneous impression that Park could be found guilty in the absence of 'wrongful action' on his part." 499 F.2d at 841-42.

Since there is then a substantial probability that the jury convicted Park solely on the basis of his corporate status, the conviction cannot stand. "A conviction ought not to rest on an equivocal direction to the jury on a basic issue." *Bollenbach* v. *United States,* 326 U.S. 607, 613 (1946).

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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